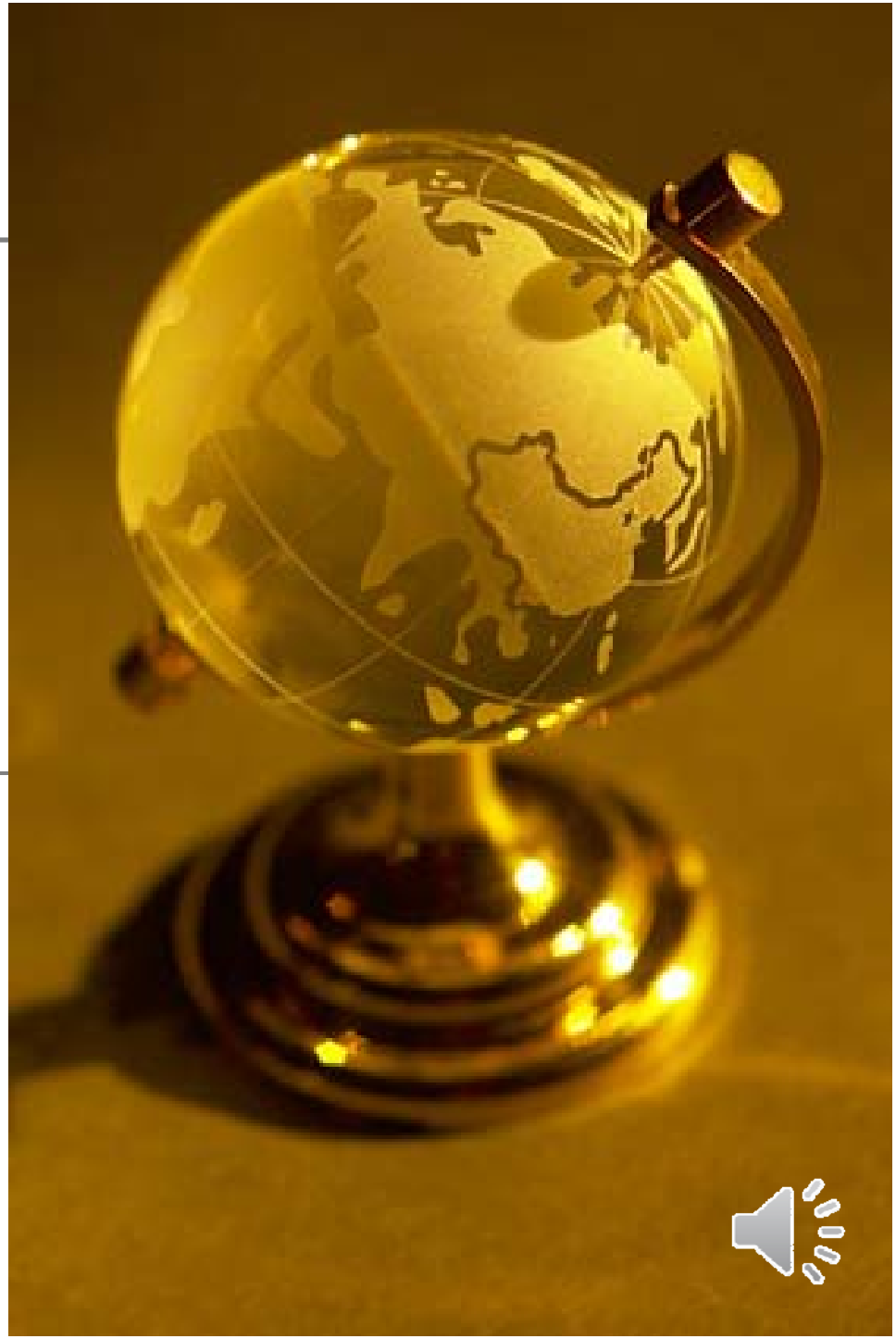
Q U E S T

The New ISO 9001:2015



Presented by
Peter Merrill

www.questmgt.com

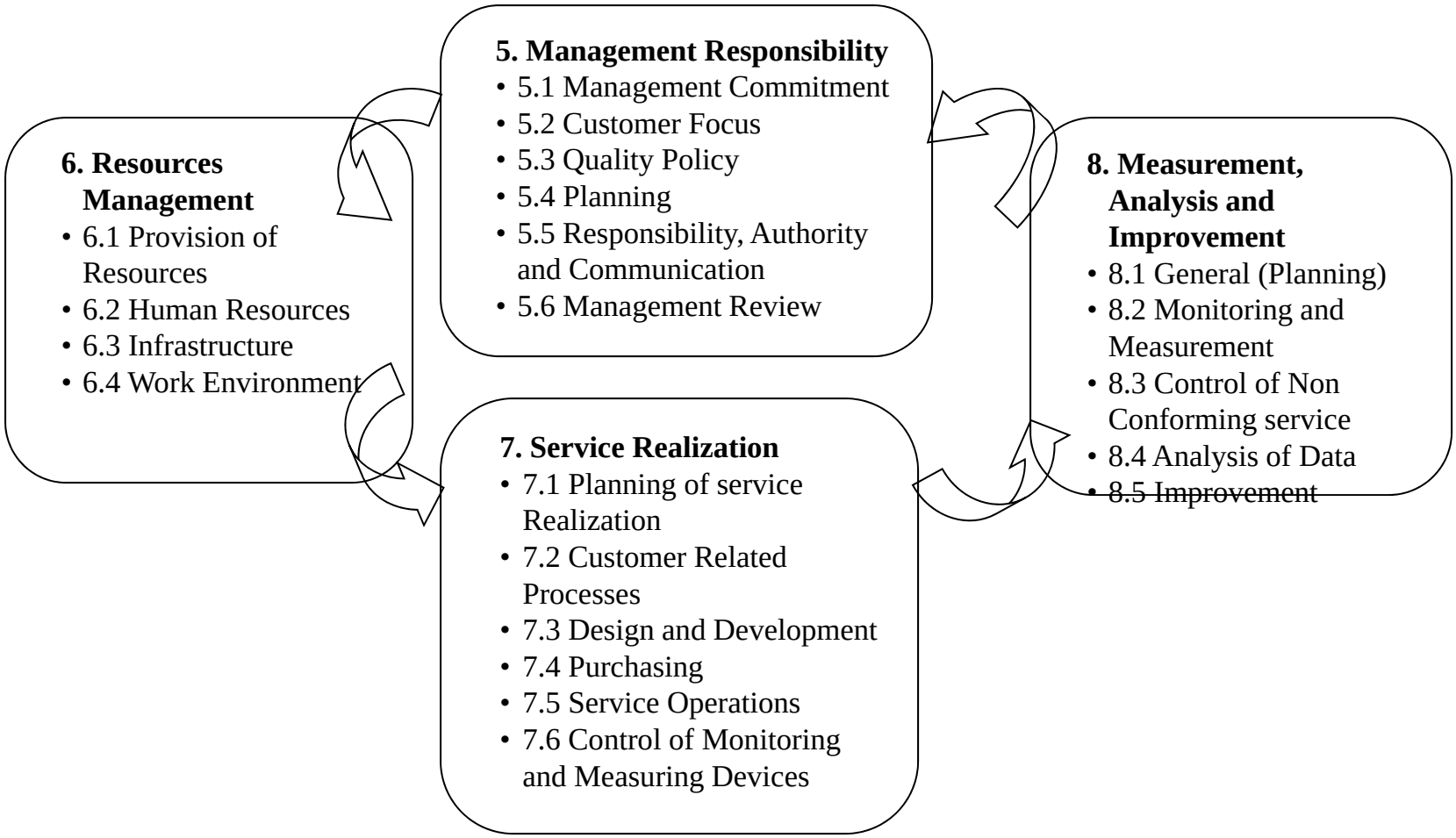
Structural changes

- High Level Structure (All ISO Mgt Systems)
  - QMS, EMS, IT security etc.
  - standard core text and structure
- Inclusion of services
- Organizational context
- Fewer prescribed requirements
- No Automatic Exclusions
- Management Review moved to ‘Monitoring’

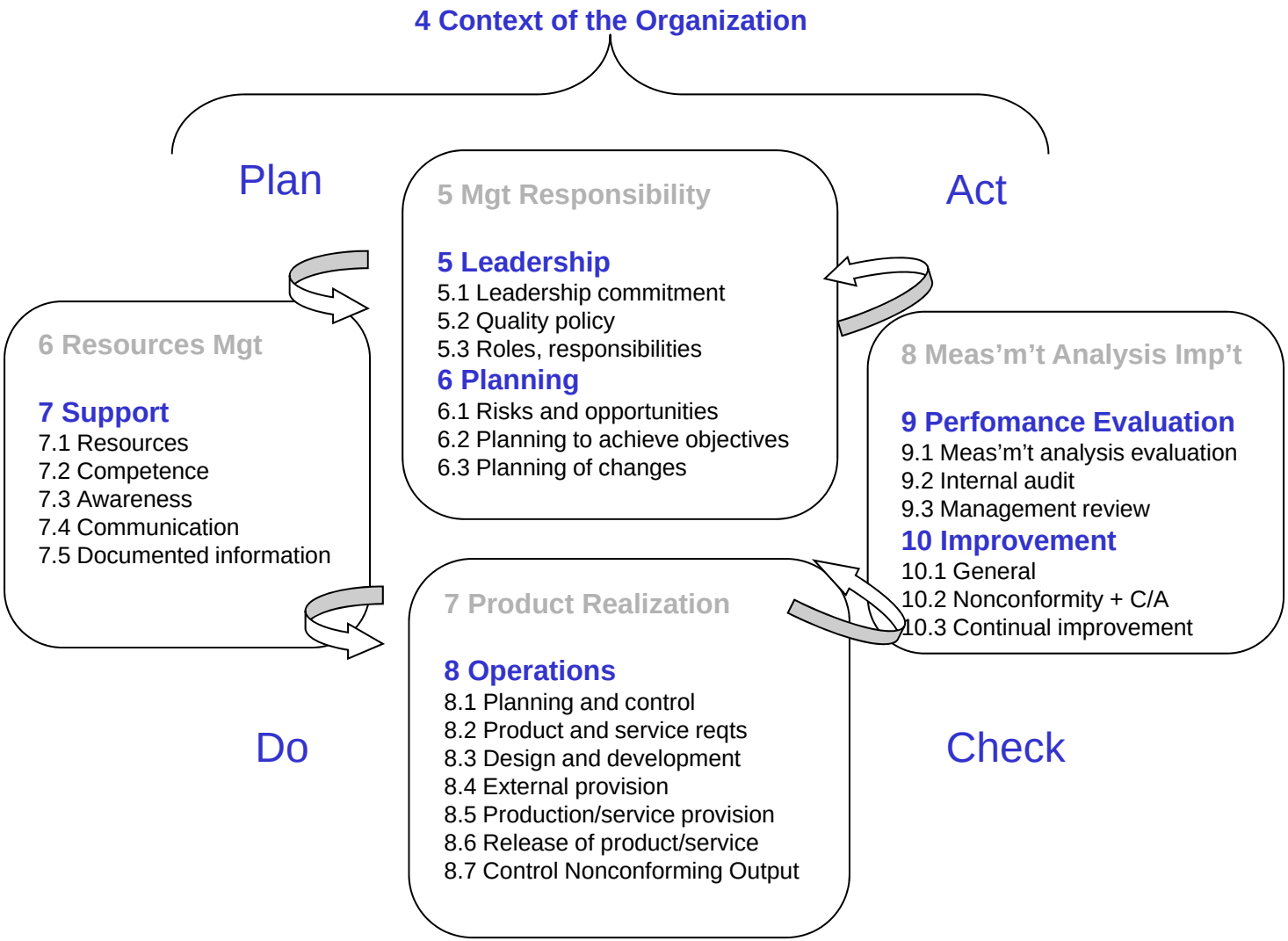
Content changes

- Risk-based thinking
  - replaces preventive action
- ‘Documented information’
  - replaces ‘documents and records’
- ‘External provision
  - Replaces ‘Purchasing and Outsourcing’
- Increased ‘Leadership’ requirements
- Management representative
  - Title removed

ISO 9001:2008 Flow



ISO 9001:2015 Structure



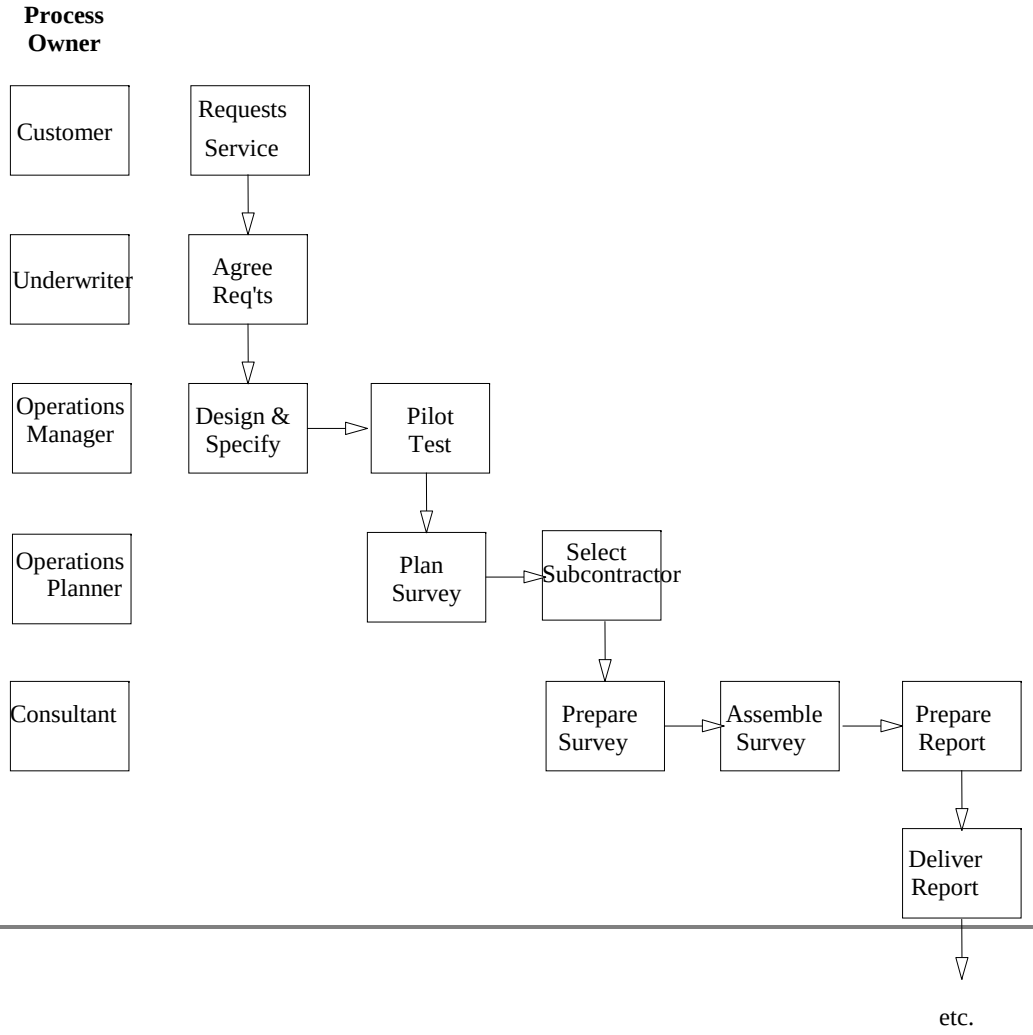
4 Context of the organization

- 4.1 The organization and its context
  - Strategic issues
- 4.2 Needs/Expectations interested parties
  - Not just customers
- 4.3 Scope of the QMS
  - Define Boundaries - Exclusions
- 4.4 QMS and its processes
  - As 9001:2008 §4.1

4.1 Context Issues for External Risk

Context Issues (Examples)	Impact (1-5)	Probability (1-5)	Detectability (1-5)	Impact x Probability ÷ Detectability
Technology				
Exchange rate				
Competition				
Market				
Economy/Oil Price				
Legislation				
Vendors				
Labour Market				
etc. etc.				

Process Map for Internal Risk Points



Some Causes of Internal Risk

- Low Competency
- Frequent Change of Persons
- Task Performed Infrequently
- Complex Process
- Old Equipment (i.e. Failure) or
- Unclear Customer Requirements?

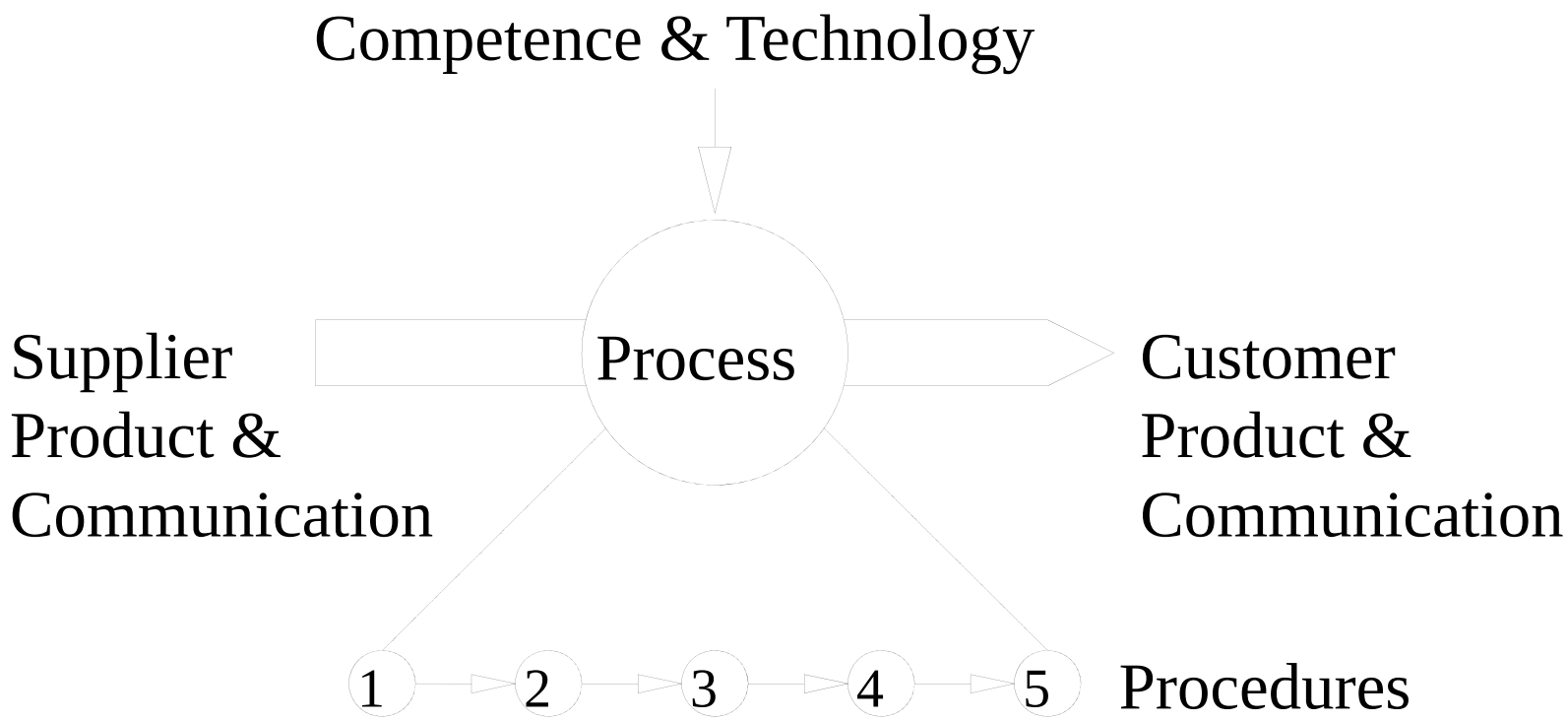
5 Leadership

- 5.1 Leadership and commitment
  - Accountability, awareness, engagement
- 5.2 Quality policy
  - similar to 9001:2008. + ‘applied’
- 5.3 Roles, responsibilities and authorities
  - QMS Reporting (Mgt Rep title removed)

6 Planning for the QMS

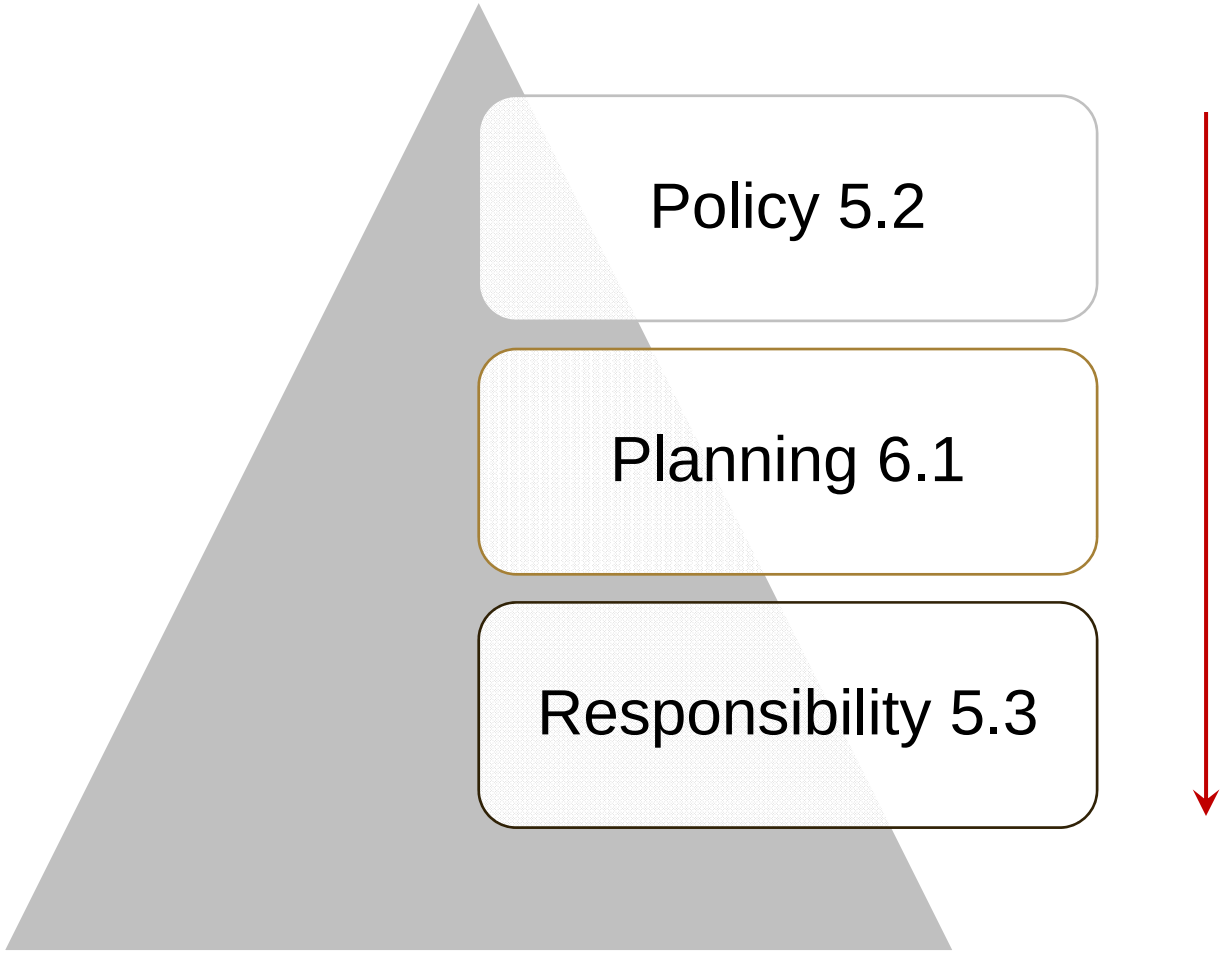
- 6.1 Address risks and opportunities
  - QMS ability to achieve intent, mitigate risk.
- 6.2 Objectives + planning to achieve them
  - Measurable, link to policy, updated
  - Resources to meet objectives, evaluate results
- 6.3 Planning of changes
  - Purpose of change
  - Resource and responsibilty

6.1 Controlling Areas of Risk



ISO 9001:2015 requires *processes are controlled* (See 8.5.1)

6.2 Cascade of Objectives



7 Support

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documents

7 Support; 7.1 Resources

- 7.1.1 General
  - Resource constraints, external resources
- 7.1.2 People
  - Provide necessary persons
- 7.1.3 Infrastructure
  - Information and communication technology
- 7.1.4 Environment for operating processes
  - As 9001:2008 §6.4
- 7.1.5 Monitoring and measuring resources
  - Calibration. (Resources implies people + competence)
- 7.1.6 Organizational knowledge
  - Knowledge acquisition and management

7.1.6 Organizational knowledge

- determine knowledge for process operation
- maintain knowledge, make it available.
- address changing needs and trends,
- how to acquire additional knowledge.

- consider;
- internal sources
  - learning from failure and success,
  - experts within the organization
- external sources
  - standards, academia, conferences,
  - customers or providers

7.2 Competence

- Competence;
- The ability to apply knowledge to achieve intended results

- determine the necessary competence of person(s)
- take actions to acquire competence,
- evaluate the effectiveness of actions taken:
- actions can include,
  - training, mentoring, hiring competent persons.
- retain documented evidence of competence.

7.3 Awareness

- Persons shall be aware of:
- Quality policy; relevant quality objectives;
- Contribution to the effectiveness of the QMS,
- Implications of not conforming with requirements.

7.4 Communication

- Determine internal and external
- QMS communications
- what will be communicated:
- when to communicate;
- with whom to communicate;
- how to communicate.

7.5 Documents

- 7.5.1 General
- The extent of documents for a QMS can differ due to:
  - organization size, process complexity, competence.

- 7.5.2 Creating and updating
- Ensure identification, review and approval.

- 7.5.3 Control of documents
  - ensure availability, confidentiality
  - address distribution, access, storage and preservation,
  - legibility; control of changes and disposition.

- Documents of external origin shall be controlled.

New wording – focus on information

Document	→	*Maintain Documented Information*
Record	→	*Retain Documented Information*

Documentation Requirements

- ISO 9001:2015 requires
- 'documented information' to be maintained;
  - Defining boundaries and applicability of QMS (see 4.3)
  - Defining the scope of the QMS (see 4.3)
  - Justifying any requirement not applicable (see 4.3)

- Organization decides
- which supporting information to document;
  - Supporting the operation of the organizations processes (See 4.4.2).
  - Necessary for the effectiveness of the QMS. (see 7.5.1)
  - Describing the interaction between the processes (See 4.4.1)

- *demonstrate that processes are controlled* (See 8.5.1).

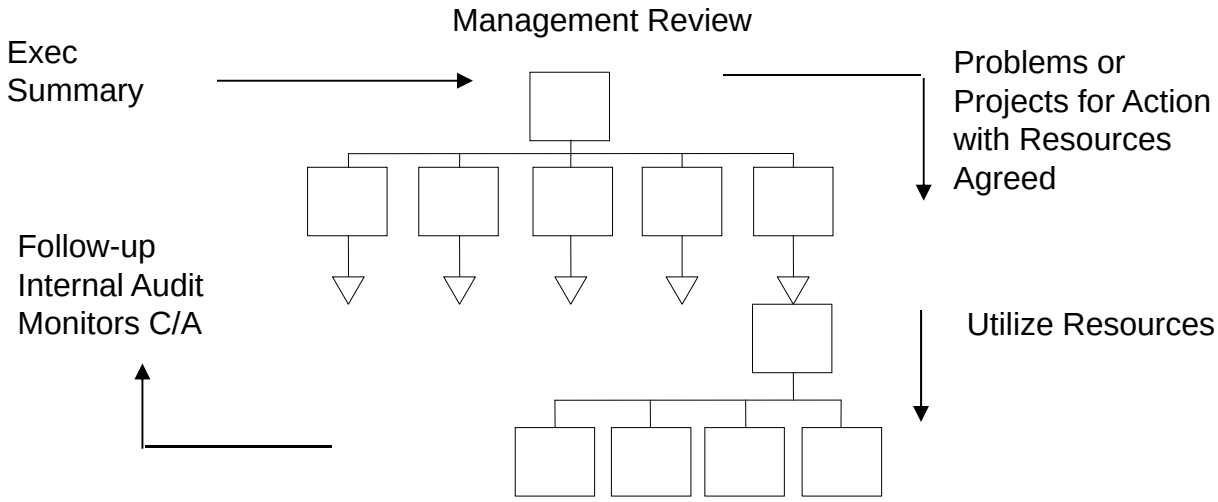
8 Operation Clauses (ISO9001:2008 §7)

- 8.1 Operational planning and control
- 8.2 Requirements for products + services
- 8.3 Design and development
- 8.4 Externally provided products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconformity

9 Performance evaluation clauses

- 9.1 Monitoring, measurement, analysis, evaluation
  - 9.1.1 General
  - 9.1.2 Customer satisfaction
  - 9.1.3 Analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

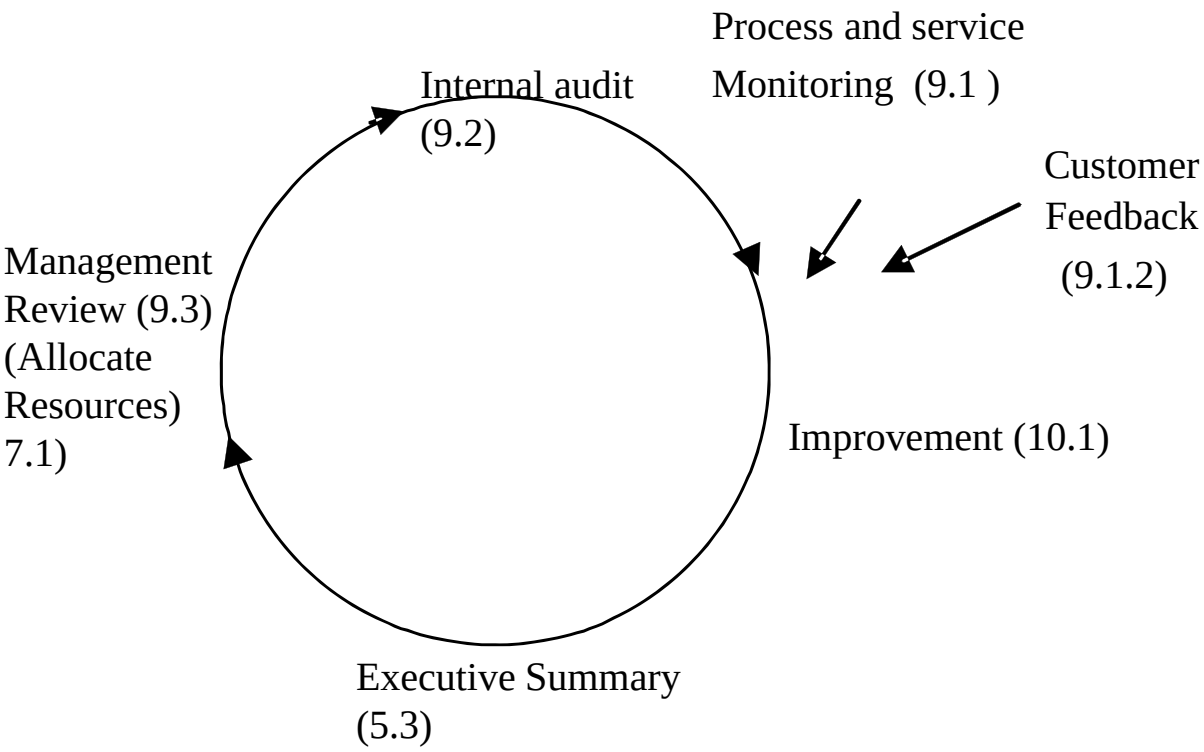
Link Audit to Management Review



10 Improvement

- 10.1 General
  - Similar to 9001:2008 §8.5.1
- 10.2 Nonconformity and corrective action
  - Similar to 9001:2008 §8.5.2
  - Addition of complaints
- 10.3 Continual improvement
  - Link to analysis, evaluation, management review
  - Address underperformance

The Improvement Cycle



ISO 9001:2015 Certification Transition Timeline

Strategy Stages

- Phase 1: Management Planning
- Phase 2 Quality System Development
- Phase 3: Assessment and Registration

Phase 1: Management Planning

MONTH	ACTIVITY
Feb	Gap Analysis
	Gap Analysis Report
	Leadership Workshop
Mar	Business Context and Interested Parties
	Business Map and Scope
	Internal Risk
	Leadership set Objectives,
Apr	Measurement at Risk Points

Phase 2 Quality System Development

MONTH	ACTIVITY
May	Quality Manual
	Employee Awareness
Jun	Customer Satisfaction Measurement
	Procedure Development (Risk)
Jul	N/C Product and Continual Improvement
	Link C/A + Audit to Management Review

Phase 3: Assessment and Registration

MONTH	ACTIVITY
Aug	Internal Audit Training
Sep	Internal Auditing
	Refine Processes and Objectives
Oct	Preliminary Assessment
	System Adjustments
Nov	Registration Audit

ISO 9001:2015 AND ISO 14001:2015 ---- NEW CERTIFICATION AND UPGRADE CERTIFICATION PROCESS

Presented By:
Karen Bakker, Vice President of Operations

WHEN YOU NEED TO BE SURE

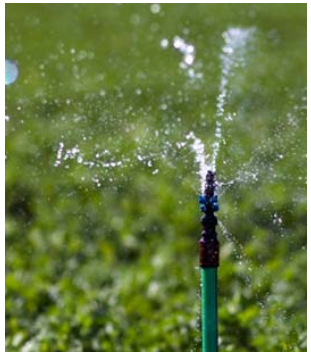
SGS

ABOUT SGS

Nº1
WORLD LEADER

80,000
EMPLOYEES

1,650
OFFICES AND LABORATORIES

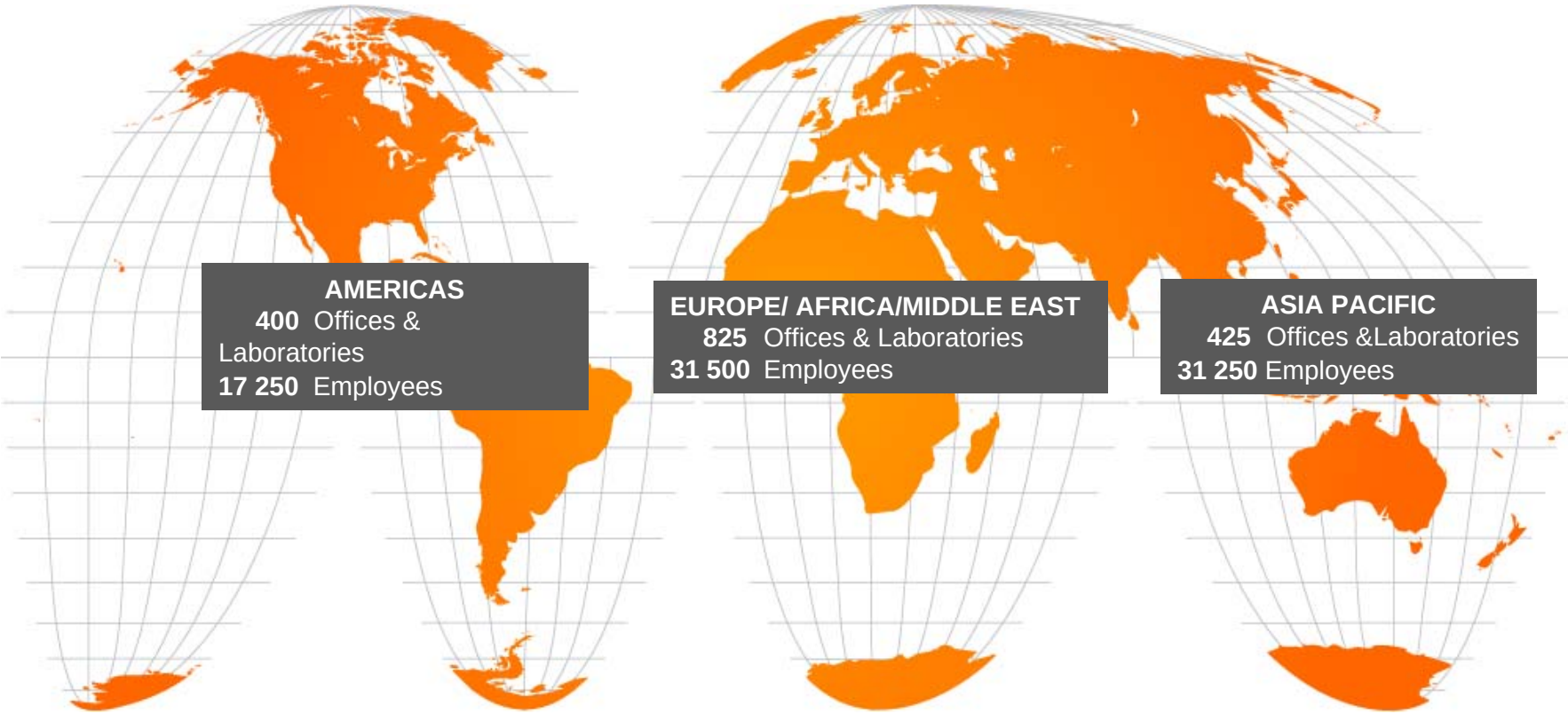


14
GLOBAL INDUSTRIES

GLOBAL SERVICE
LOCAL EXPERTISE

SERVING 130 COUNTRIES

GLOBAL REACH AND LOCAL SUPPORT



- **80,000 employees worldwide**
- **Over 1 650 offices and laboratories operating in 130 countries**

CERTIFICATION AND BUSINESS ENHANCEMENT (CBE)
CERTIFICATIONS

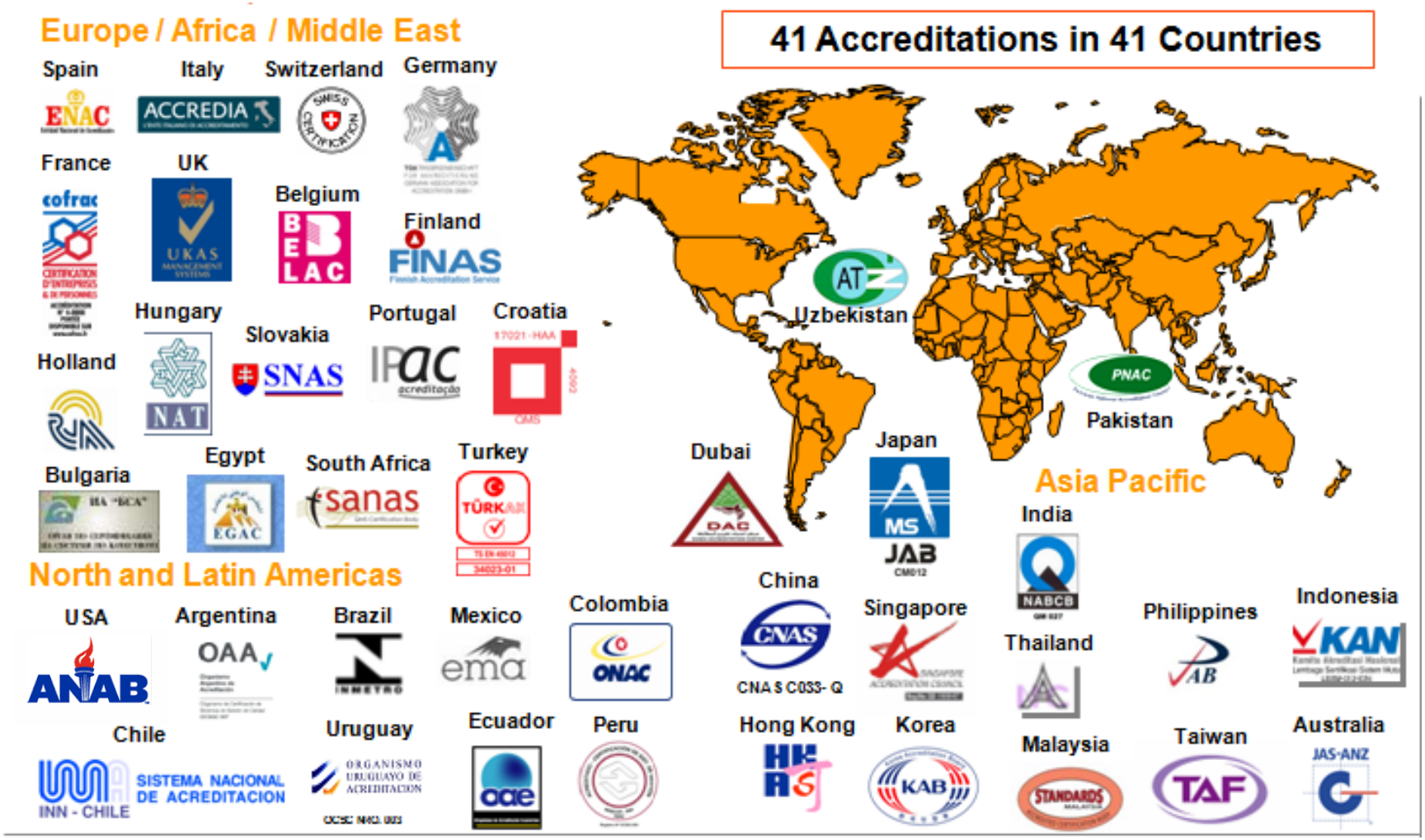
GENERIC STANDARDS

- ISO 9001 (Quality Management Systems)
- ISO 14001 (Environmental Management Systems)
- OHSAS 18001 (Occupational Health & Safety)
- ISO 50001 (Energy Management Systems)
- ISO 14064 (Green House Gas Verification)
- ISO 27001 (Information Security Management Systems)
- ISO 22301 (Business Continuity Management)
- ISO 20000 (Information Technology Management)
- SA 8000 (Social Accountability)
- PAS 2050 (Carbon Footprint)
- ISO 10002 (Complaint Management)
- Integrated Management Systems (IMS)

INDUSTRY STANDARDS

- **Oil & Gas** – ISO 29000
- **Automotive** – ISO/TS 16949
- **Aerospace** – AS 9100, EN 9100, AS 9110
- **Medical Device** – ISO 13485, CE Directives, Local Regulatory
- **Food Safety** - ISO 22000, FSSC 22000, HACCP, GMP
- **Pharmaceutical** – GMP Audit Solutions
- **Cosmetics** – ISO 22716
- **Bio-fuels** – Bonsucro, ISSC, RSPO, RTS
- **Forests & Wood** – Chain of Custody
- **Logistics & Transportation** – TAPA FSR, TAPA TSR, ISO 28000, C-TPAT
- **Electronics** – IECQ HSPM, ESD, EUP, EICC, RIOS, RS2
- **Telecommunications** – TL 9000
- **Railway** – IRIS
- **Finance** – ISO 22222

SGS : THE LARGEST ACCREDITED CERTIFICATION BODY



ISO 9001:2015 / ISO 14001:2015 ---- NEW MANAGEMENT SYSTEM IMPLEMENTATION & REGISTRATION AT A GLANCE

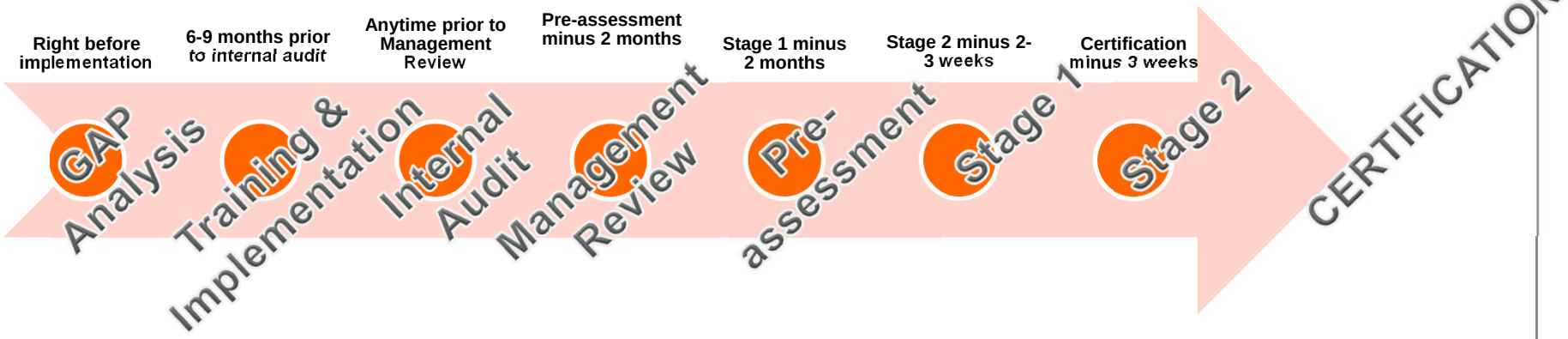
Implementation

- Gap Analysis
- Implementation
- Internal Audit & Corrective Action
- Management Review

Registration

- Pre-Assessment (Typically 2-3 months prior)
- Stage 1 Audit (Readiness Assessment – Typically 3-4 weeks prior to Stage 2)
- Stage 2 Audit (Certification Audit)
- Surveillance Audits (Annual / Semi-Annual)

ISO 9001:2015 / ISO 14001:2015 ---- NEW MANAGEMENT SYSTEM IMPLEMENTATION & REGISTRATION AT A GLANCE



ISO 9001:2015 / ISO 14001:2015 ---- NEW MANAGEMENT SYSTEM ---------- THE CERTIFICATION PROCESS
PRE-ASSESSMENT

- Summary of a Pre-Assessment

- The objective of the Pre-Assessment audit is to assess the state of your MS: (1) how your organization aligns with the requirements of the Standard; (2) that your MS conforms with the Standard; (3) any areas of your MS that require addressing prior to a Certification Audit.

Elements of a Pre-Assessment are:

- We perform a mock audit of both Stage 1 and Stage 2
- We provide a detailed report outlining findings
- Next step - Plan and Review

Types of findings – Critical and Non-Critical Findings and Opportunities for Improvement

ISO 9001:2015 / ISO 14001:2015 ---- NEW MANAGEMENT SYSTEM ---------- THE CERTIFICATION PROCESS
STAGE 1 AUDIT

- Summary of a Stage 1 Audit

- The objective of the Stage 1 audit is to review your MS documentation and to confirm: (1) the management system conforms with the applicable elements of the Standard; (2) to assess your readiness for the Stage 2 Certification audit.

- Elements of a Stage 1 Audit are:
  - We review all MS documentation and KPI's
  - We review Scope/Boundary & Regulatory requirements
  - Review availability of Planning and Implementation information
  - Review of Internal Audits and Management Reviews
  - Next step Plan and Review & Stage 2 Readiness

- Types of findings – Critical and Non-Critical Findings and Opportunities for Improvement

ISO 9001:2015 / ISO 14001:2015 ---- NEW MANAGEMENT SYSTEM ---------- THE CERTIFICATION PROCESS
STAGE 2 AUDIT

- Summary of a Stage 2 Audit

- The objective of the Stage 2 Audit is to confirm the management system: (1) conforms with the applicable elements of the Standard; (2) the organization conforms with its own policies and procedures; (3) the management system is suitable for the organization; and (4) that the management system is suitable and effective, and enables the client to achieve its own objectives.

- This is a full assessment of the implementation and effectiveness of the MS. There is a wide sample of interviews, records review, facilities tour, observations, etc. to make this determination.

- Types of findings – Major or Minor Non-Conformances, Opportunities for Improvement, and Positives

ISO 9001:2015 / ISO 14001:2015 ---- NEW MANAGEMENT SYSTEM ---------- THE CERTIFICATION PROCESS
SURVEILLANCE AUDITS

- Summary of a Surveillance Audit

- The objective of the on-going Surveillance Audits is to confirm the management system continues to conform with the applicable elements of the Standard; to confirm the organization continues to conform with its own policies and procedures; to confirm the management system is suitable for the organization; to confirm that the management system is suitable and effective, and enables the client to achieve its own objectives.
- This is a moderate assessment of the implementation and effectiveness of the MS. Moderate sample of interviews, records review, facilities tour, observations, etc. are conducted.
- Types of findings – Major or Minor Non-Conformances, Opportunities for Improvement, and Positives

ISO 9001:2015 / ISO 14001:2015 UPGRADE – **FOUR TRANSITION PATHWAYS**

1. **Transition at Renewal of Certification**
2. **Transition at Planned Surveillance**
3. **Transition between Normally Scheduled Audits (Special Audit)**
4. **Transition as a Phased Activity (over the course of Several Surveillance Audit Visits)**

- RECOMMENDED: Pre-Assessment prior to ensure readiness … and any items to address prior to Upgrade Audit.

ISO 9001:2015 / ISO 14001:2015 TRANSITION – **FOUR TRANSITION PATHWAYS**

1. Transition at Renewal of Certification

- The audit will be conducted as a full system audit to the ISO 9001:2015 and/or ISO 14001:2015 Standard including all clauses and all processes.
- Technical review and certification decision after this audit will lead to a 2015 version certificate.

2. Transition at Planned Surveillance

- The audit will be conducted as a scope extension to the ISO 9001:2015 and/or ISO 14001:2015 Standard. The focus will be on changes to the clauses/processes for the new standard.
- Appropriate time will be determined based on the organization to allow adequate time to audit the changes to the standard.
- Technical review and certification decision after this audit will lead to a 2015 version certificate retaining the current certificate expiry date.

ISO 9001:2015 / ISO 14001:2015 TRANSITION – **FOUR TRANSITION PATHWAYS**

3. Transition between Normally Scheduled Audits (Special Audit)

- The audit will be conducted as a scope extension to the ISO 9001:2015 and/or ISO 14001:2015 Standard. The focus will be on changes to the clauses/processes for the new standard.
- Appropriate time will be determined based on the organization to allow adequate time to audit the changes to the standard.
- Technical review and certification decision after this audit will lead to a 2015 version certificate retaining the current certificate expiry date.

ISO 9001:2015 / ISO 14001:2015 TRANSITION – **FOUR TRANSITION PATHWAYS**

4. Transition as a Phased Activity (over Several Audit Visits)

- This choice allows for transition throughout the cycle.
- A selection of clauses from the new standard will be audited at each event ensuring all clauses are audited in the cycle prior to issuance of a certificate to the new ISO 9001:2015 and/or ISO 14001:2015 Standard.
- SGS will work with clients to develop a plan and monitor the activity to ensure all requirements are met.
- With this choice, a client must maintain conformance to ISO 9001:2008 and/or ISO14001:2004 throughout the cycle.
- This will most likely require the most audit time over the cycle.
- The 2015 version certificate will be issued after all update audits are completed to the new requirements.

Thank you!

For more information, please contact:

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