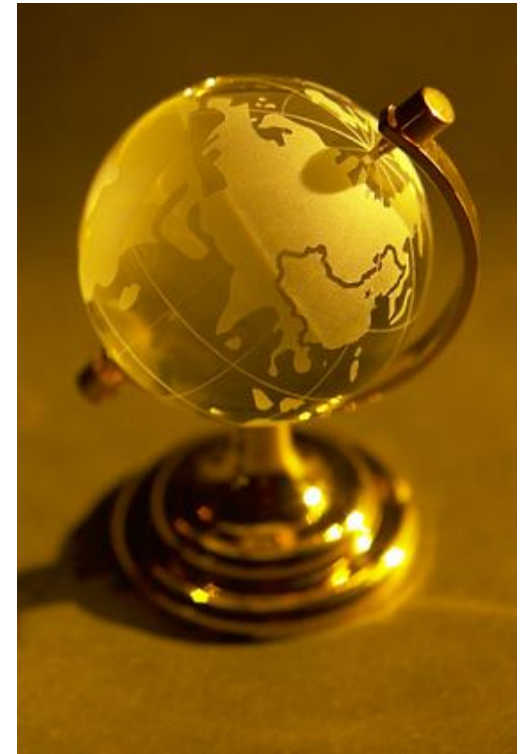


QUEST

RISK BASED THINKING
FLOWS THROUGH
ISO 9001:2015
DRIVING A FASTER,
BETTER ORGANIZATION.



Presented by
Peter Merrill
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WHEN YOU NEED TO BE SURE

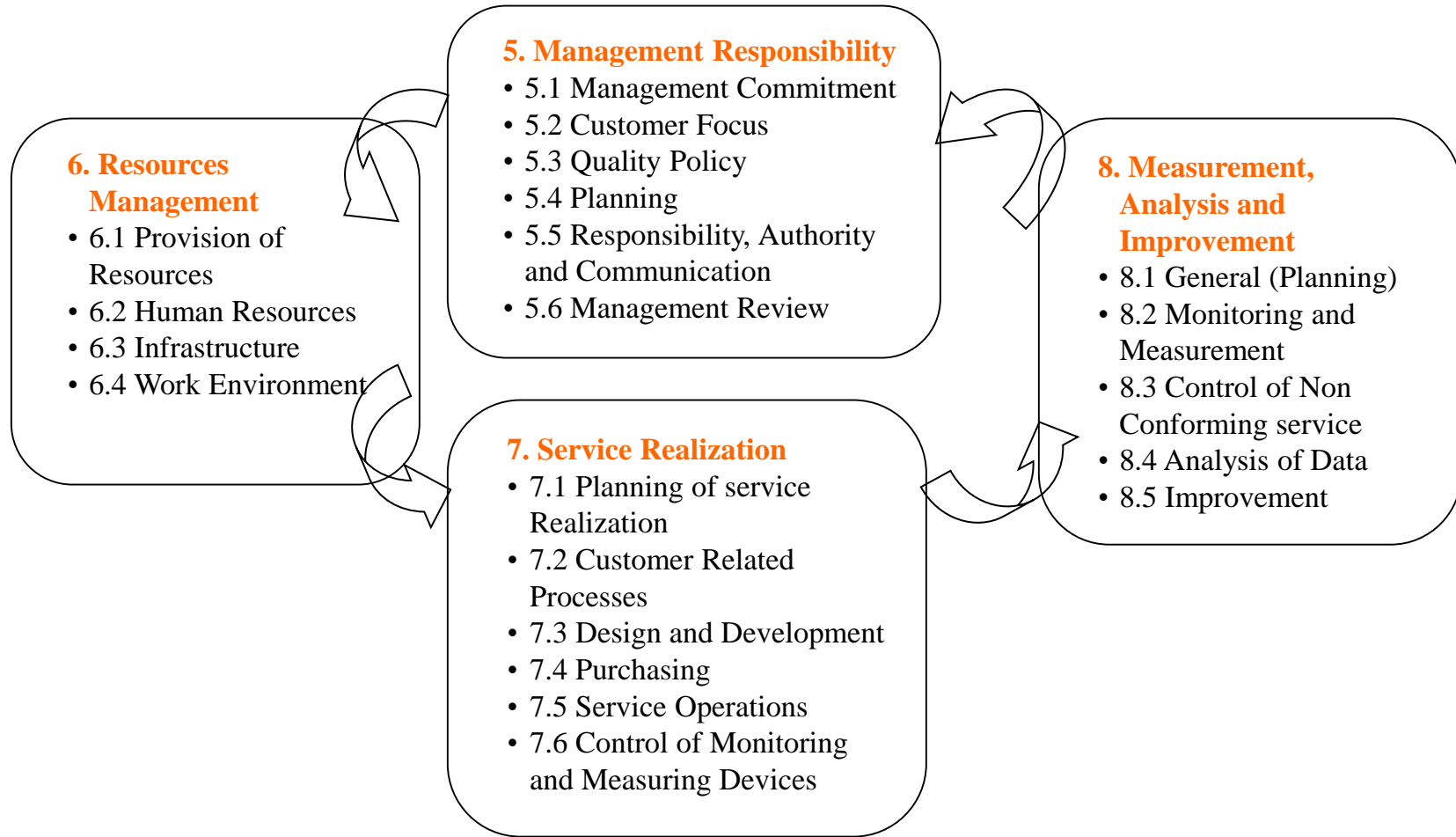


STRUCTURAL CHANGES

- 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

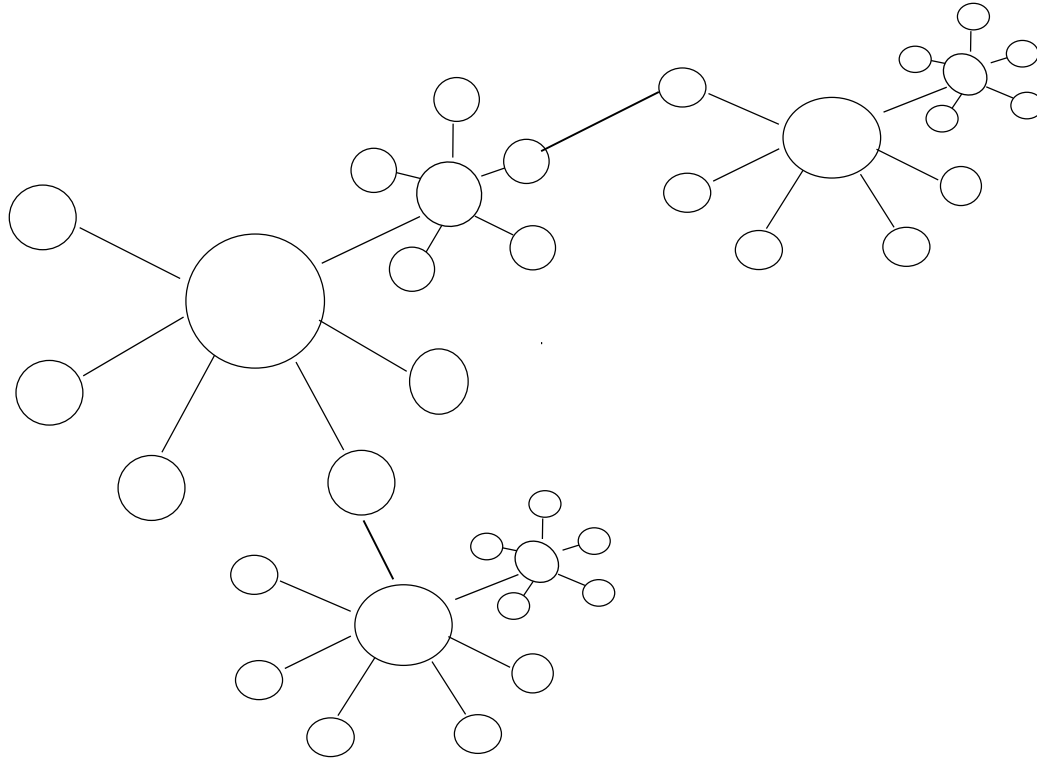
- Risk-based thinking
 - replaces preventive action
- 'Documented information'
 - replaces 'documents and records'
- 'External provision'
 - Replaces 'Purchasing and Outsourcing'
- Increased 'Leadership' requirements
- Management representative
 - Title removed



ISO 9001:2015 STRUCTURE

4 Context of the Organization





A System is 'A Set of inter-related and interacting elements
A Management System is a Network of People , Process and
Technology

4 CONTEXT OF THE ORGANIZATION

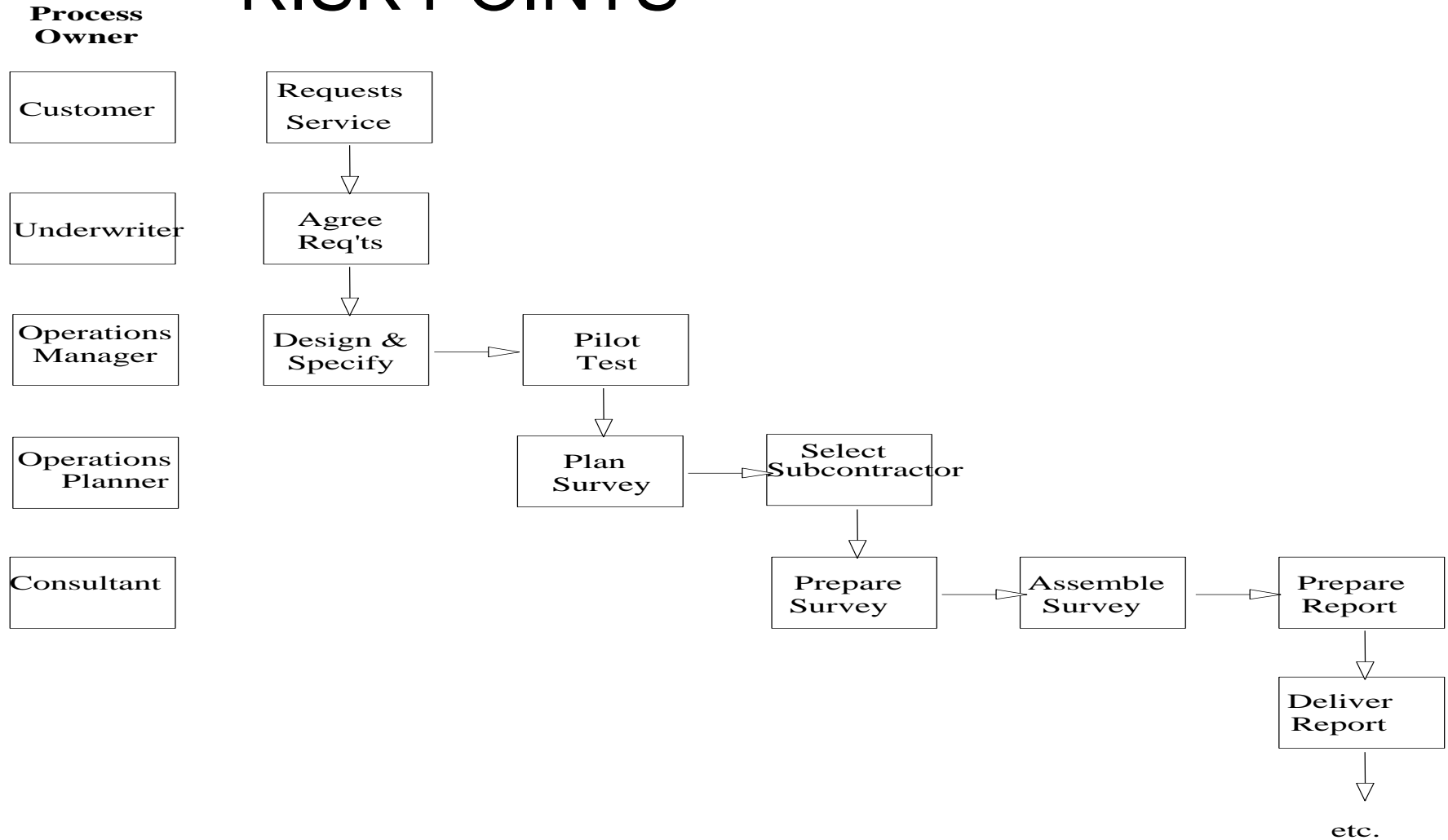
- 4.1 The organization and its context
 - Strategic issues
- 4.2 Needs/Expectations interested parties
 - Not just customers
- 4.3 Scope of the QMS
 - Define Boundaries - Exclusions
- 4.4 QMS and its processes
 - As 9001:2008 §4.1

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

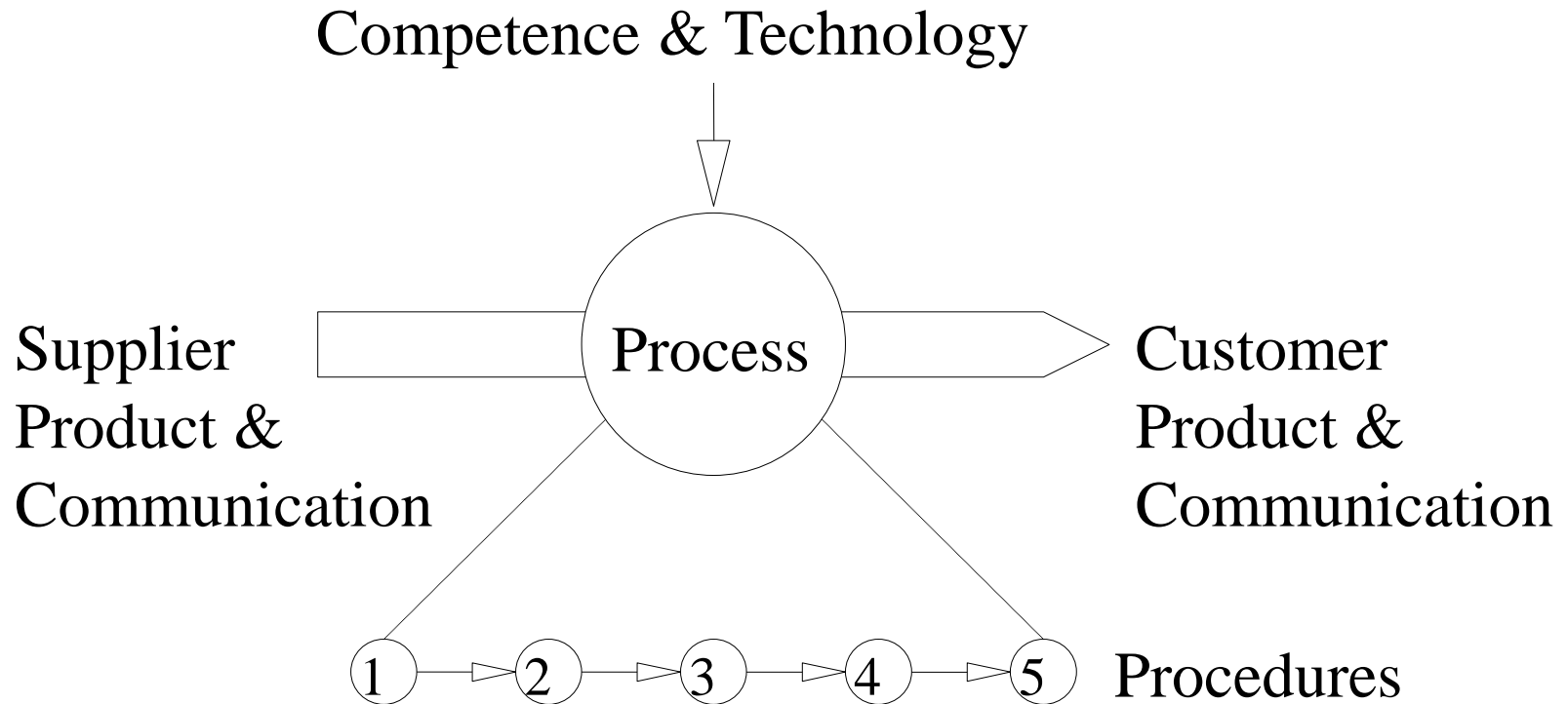
- Low Competency
- Frequent Change of Persons
- Task Performed Infrequently
- Complex Process
- Old Equipment (i.e. Failure) or
- Unclear Customer Requirements?

- 5.1 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 responsibility

6.1 CONTROLLING AREAS OF RISK



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

6.2 CASCADE OF OBJECTIVES



PLANNING TO ACHIEVE OBJECTIVES (6.2.2)

Objective	What is to be done	Resources needed	Who is responsible	When it will be done	How results will be evaluated

- 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.
- 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

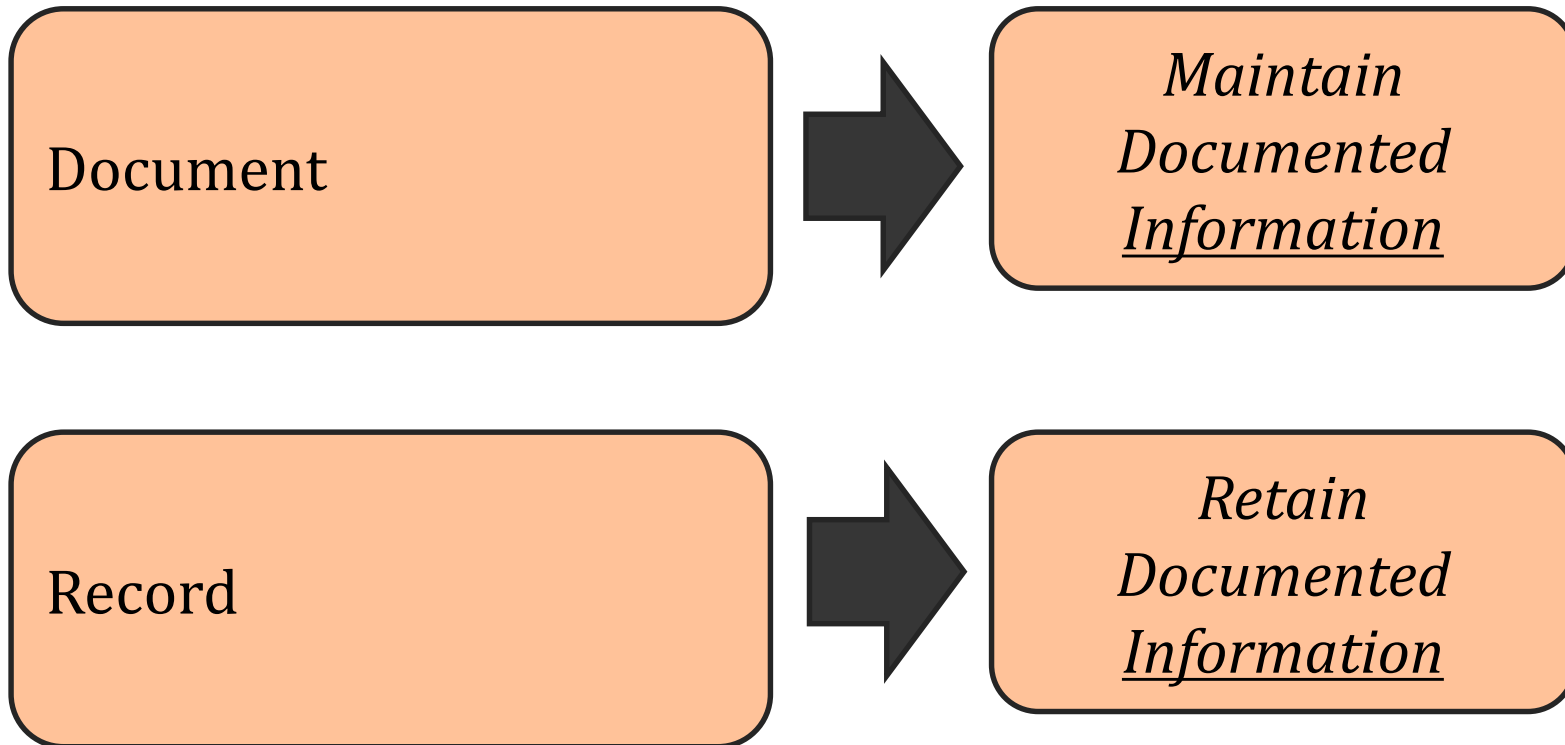
- determine the necessary **competence** of person(s)
- take actions to **acquire competence**,
- evaluate the effectiveness of actions taken:
- actions can include,
 - training, mentoring, hiring competent persons.
- retain **documented evidence of competence**.

- 7.5.1 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.



- 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

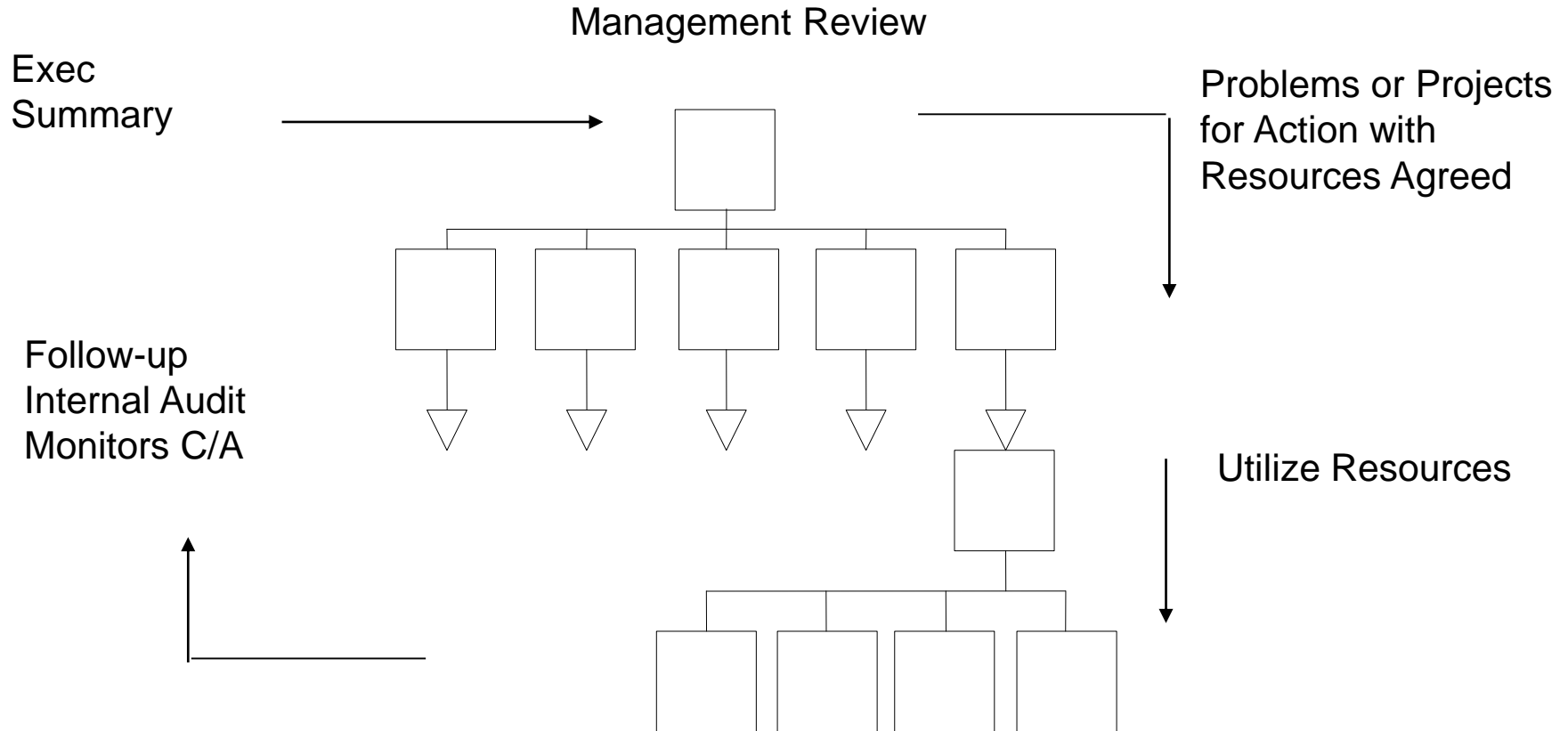
9 PERFORMANCE EVALUATION CLAUSES

- 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

FEED RESULTS TO MANAGEMENT REVIEW



■ 10.1 General

- Similar to 9001:2008 §8.5.1

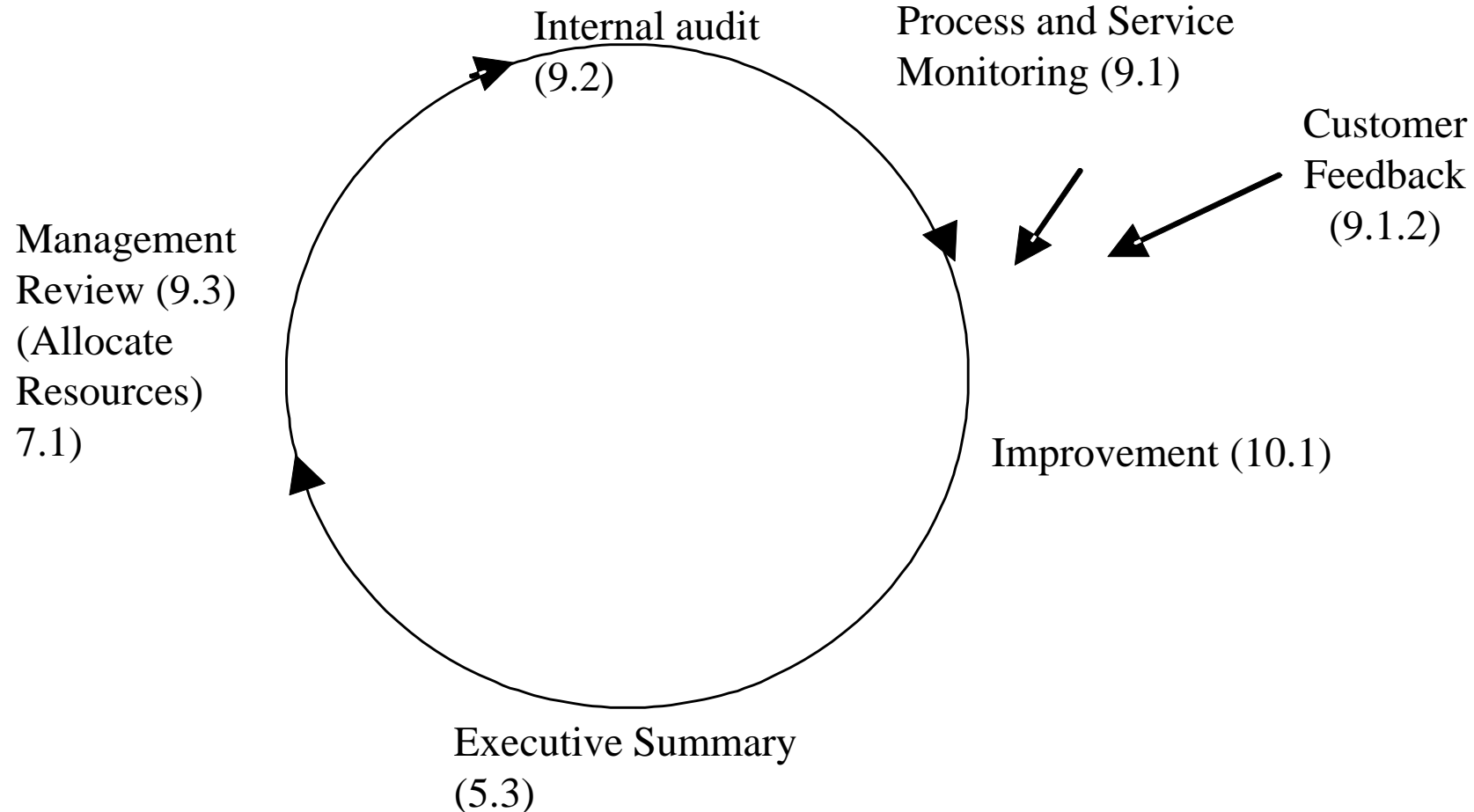
■ 10.2 Nonconformity and corrective action

- Similar to 9001:2008 §8.5.2
- Addition of complaints

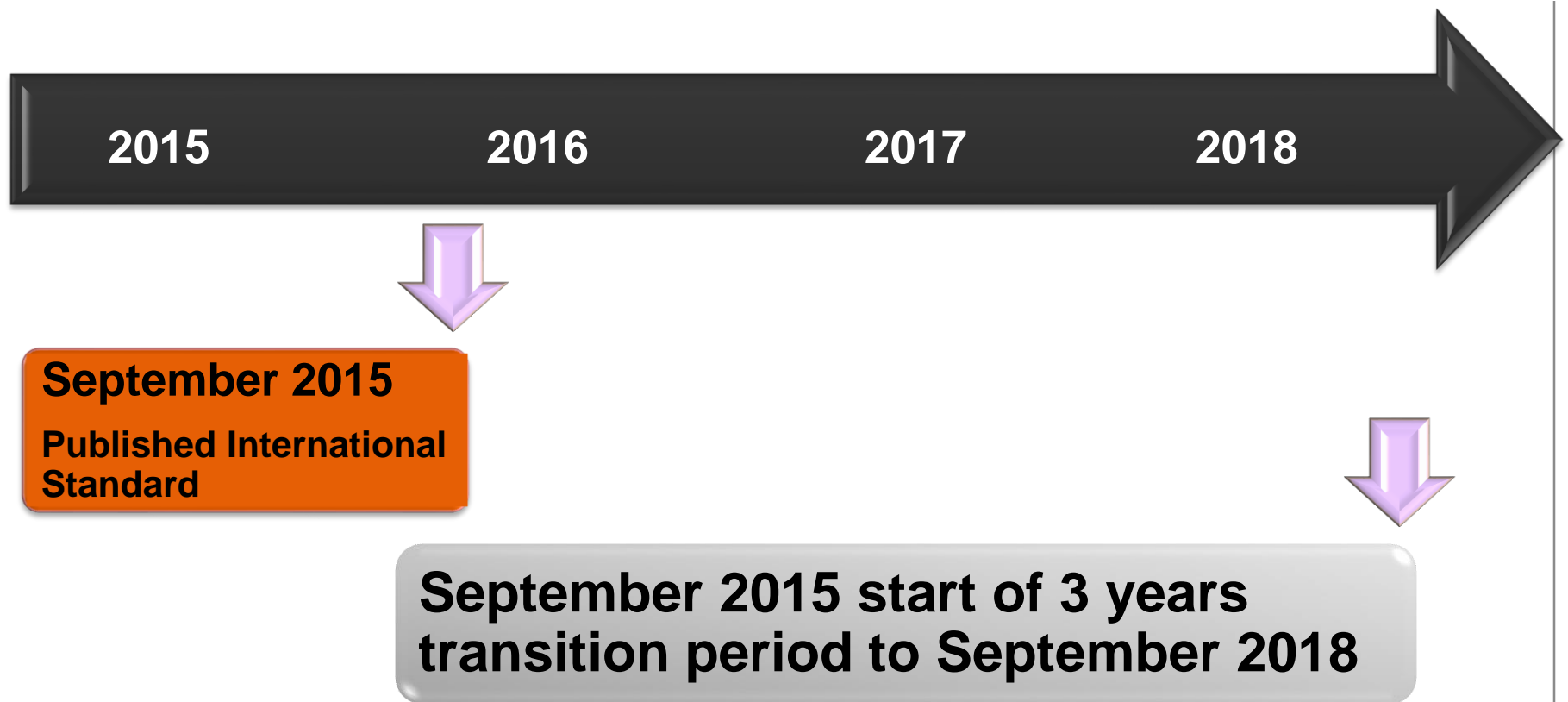
■ 10.3 Continual improvement

- Link to analysis, evaluation, management review
- Address underperformance

THE IMPROVEMENT CYCLE



ISO 9001:2015 CERTIFICATION TRANSITION TIMELINE



ISO 9001:2015 Implementation Timetable

Phase One: Management Planning

Gap Analysis	■																		
Leadership Workshop		■																	
Strategic Plan			■																
Measurement Plan			■																
Support Reqts				■															

Phase Two: Quality System Development

Manual Development					■	■													
Employee Awareness							■												
Service Issues							■												
Procedure Revisions								■	■										
Corrective Action									■										
Customer Satisfaction				■			■		■										

Phase Three: System Assessment

Internal Audit Training										■									
Selection of Registrar									■	■									
Internal Audit											■	■							
Refine Procedures												■							
Prelim. Assessment													■						
System Adjustment														■					
Main Audit																■			
Registration Confirmed																	■		

SGS

THANK YOU

Questions?

Q U E S T

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