

Preparatory Program on

# ISO 9001 : 2015 Quality Management System

Edition #  
5



QMS

Focus  
on  
Quality

Facilitator	Firm	Contact details	
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## S O P for Training Program on

# ISO 9001 : 2015

Type of Program :-

- Technical
- Management
- Behavioral

	Min.	Max.
Hours	7	9
No. of Participants	15	30

Mixed Group :  Yes  No

### Program Objectives

To familiarize the participants to understand the over all requirements of ISO 9001:2015, the Process approach and the key changes in the latest version.

To provide adequate familiarity on ISO 9001 which is the Foundation for **ISO / TS 16949** too !

#### Performance Indicators :

##### Short-term :

- 📄 Post Test Marks
- 📄 Program feed-back

##### Long-term :

- 📄 Enhanced QMS knowledge
- 📄 Understanding the system intent
- 📄 Foundation for systems auditing.



### Process

#### Methodology :

- ▶▶ Class Room Lecture
- ▶▶ Brain storming on requirements
- ▶▶ Situations analysis
- ▶▶ Group Presentation
- ▶▶ Accelerated learning
- ▶▶ Idea building through G D
- ▶▶ Examples for QMS documentation

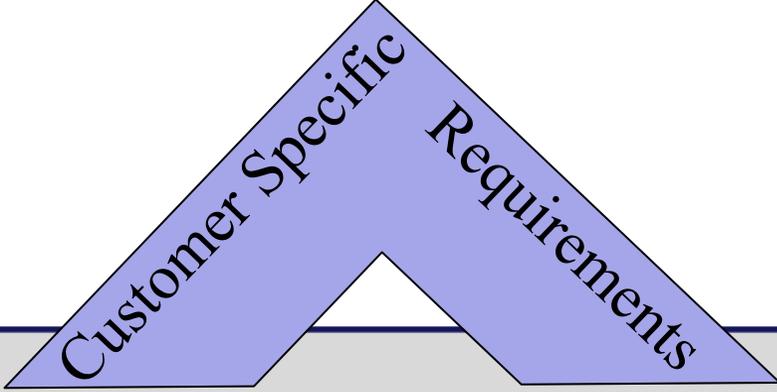
#### Structure :

- ▶▶ Ice Breaking
- ▶▶ Pre Test
- ▶▶ Explanations on each Clause
- ▶▶ Group Discussion on requirements
- ▶▶ Post Test & Evaluation
- ▶▶ Clarification of Post Test
- ▶▶ Verbal Feed Back
- ▶▶ Commitment on system adherence
- ▶▶ Written Feed Back



### Deliverables

- System based management
- Back ground of ISO
- Key Terms & definitions
- Risk Based Approach : A Close look
- QMS - overall intent
- 7 Management principles
- PDCA cycle in QMS
- Process approach with examples
- Turtle diagram for process approach
- ISO 9001 : 2015 requirements
  - Clause 1 to Clause 10
  - Linkage between clauses
- Key changes in the latest version





# Situation *Analysis*



A meeting is scheduled by your Top management for the next 2 weeks on daily basis.  
You are supposed to attend daily for 90 minutes from 10 am onward.  
The challenge is that, you are to reach the Meeting hall, by **CROSSING A VERY BUSY ROAD !** The road looks to be too busy with lot of Cars, Buses and Auto-rickshaws !

**Objectives**

**Risks**

**Opportunities**

**Strategic Planning**



➤ **What ?**

➤ **Why ?**

➤ **How ?**

# Risk Based Thinking.....

## Situation Analysis



- Is NOT a Negative Approach !
- Is part of Planning !
- Creates a Strong Knowledge base !
- Helping in reaching our Objectives !
- Provides Alternate plans too !

# Quality Management System



**Objectives**

**Risks**

**Opportunities**

**Strategic  
Planning**

# Team Based Exercise

Ex # 2



## Type of Exercise :

- Situation Analysis
- Choose the best Answer
- Word Puzzle
- Matching of terms
- Mapping & GD

## Focus

- ❖ Objectives
- ❖ Risks
- ❖ Opportunities
- ❖ Strategic Planning
- ❖ Worksheet available in the Course material



## Self Evaluation

*Please Choose the Best Answer !*

#	Question / Statement	Your Response	Evaluation
1	QMS to particularly address on Risk & Opportunities also a) True b) False		
2	Which ONE of the following statement must be considered as a Risk ? a) In the market, there is a big demand for one particular Equipment, which is produced by us presently. b) Customer needs 5000 more parts from next year onward. We have 4 months to plan. c) Budget must be increased by 50 Lacs & Organization needs fund from the Banker d) None of the above		
3	Risk is related to the Objectives & Opportunities are related to the Results. a) True b) False		
4	Risk is generally Negative in nature a) True b) False		
5	Risk shall be evaluated based on – a) Severity b) Frequency c) Present Controls available d) All the above		

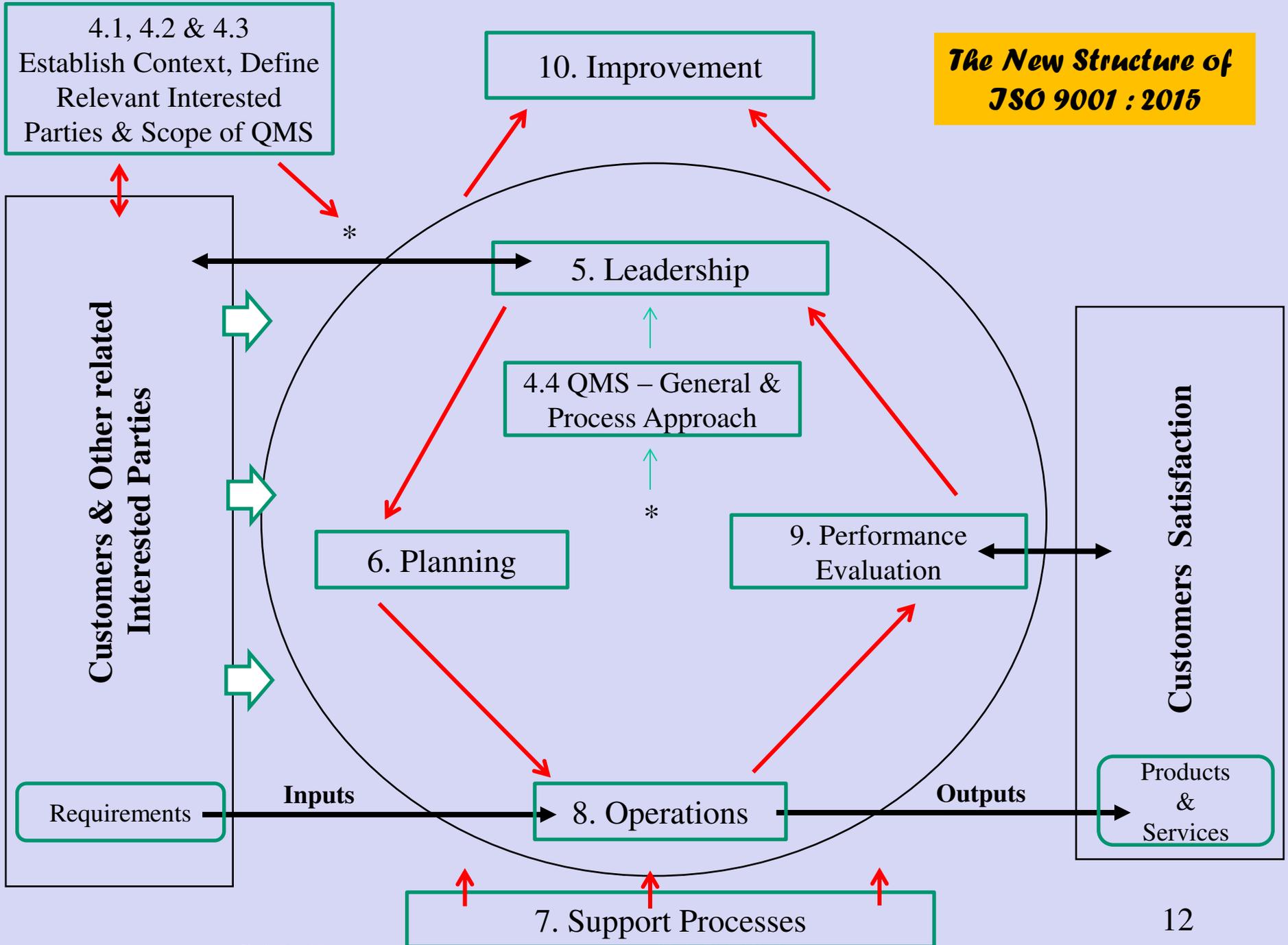
#	Question / Statement	Your Response	Evaluation
6	Opportunities are generally related to the - a) Risks involved in them b) Objectives set already c) None of the above		
7	QMS documentation is part of - a) 'Plan' element. b) 'Act' element. c) None of the above		
8	In every Failures - a) Risk levels will be the same b) Risk levels may be different c) There is no relationship between the Risk levels & Failures		
9	Strategic planning will deal with both Setting of Goals & Means to reach those goals. a) True b) False		
10	QMS Wants a Risk Based Thinking Process. a) True b) False		

Q M S



***Some Fundamentals  
at a Glance !***

**The New Structure of  
ISO 9001 : 2015**



## Situations Analysis

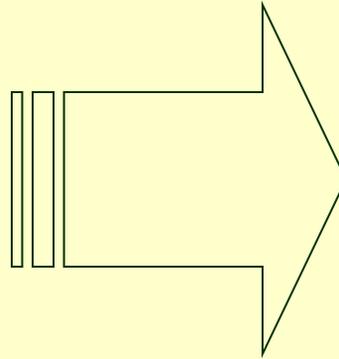
# 7

## Quality Management Principles

- ❑ *This exercise will familiarize us to 7 Management Principles !*
- ❑ *There are 18 different situations !*
- ❑ *Nothing like completely right or completely wrong !*
- ❑ *Only sample is for demo !*

1. Customer Focus
2. Leadership
3. Engagement of People
4. Process Approach
5. Improvement
6. Evidence based Decision making
7. Relationship Management

*Place & Customers*



*Product*



*Stated*

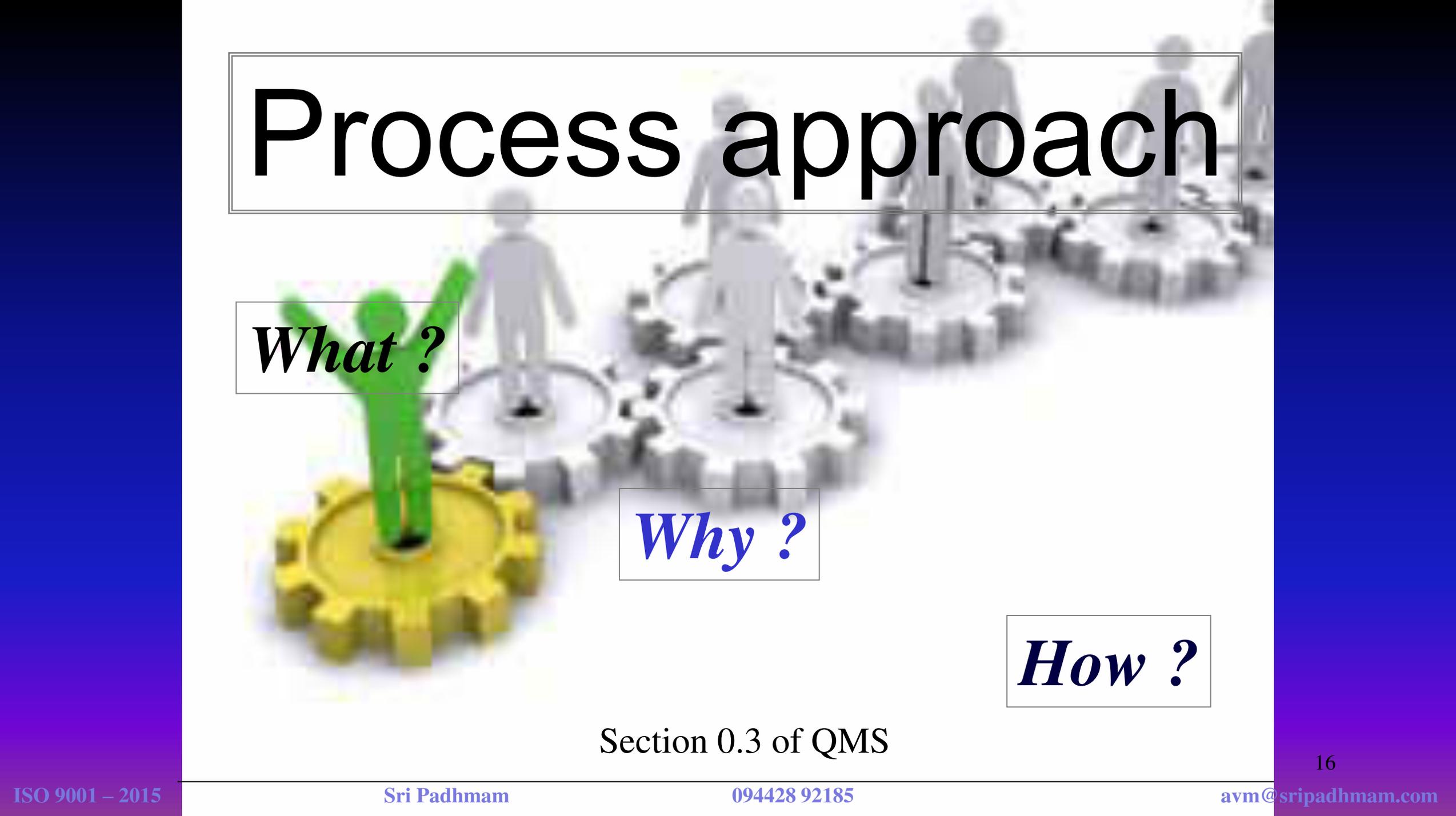
*Implied*

*Obligatory*

# Changes in the Terms in 5<sup>th</sup> Edition

#	ISO 9001 : 2008 ( 4 <sup>th</sup> Edition )	ISO 9001 : 2015 ( 5 <sup>th</sup> Edition )
1	Products	<i>Products &amp; Services</i>
2	Exclusions	<i>“Removed from the Standard”</i>
3	Documents & Records	<i>Documented Information</i>
4	Work Environment	<i>Environment for the Operation &amp; Process</i>
5	Purchased Product	<i>Externally provided Products &amp; Services</i>
6	Supplier	<i>External Provider</i>

# Process approach



*What ?*

*Why ?*

*How ?*

Section 0.3 of QMS

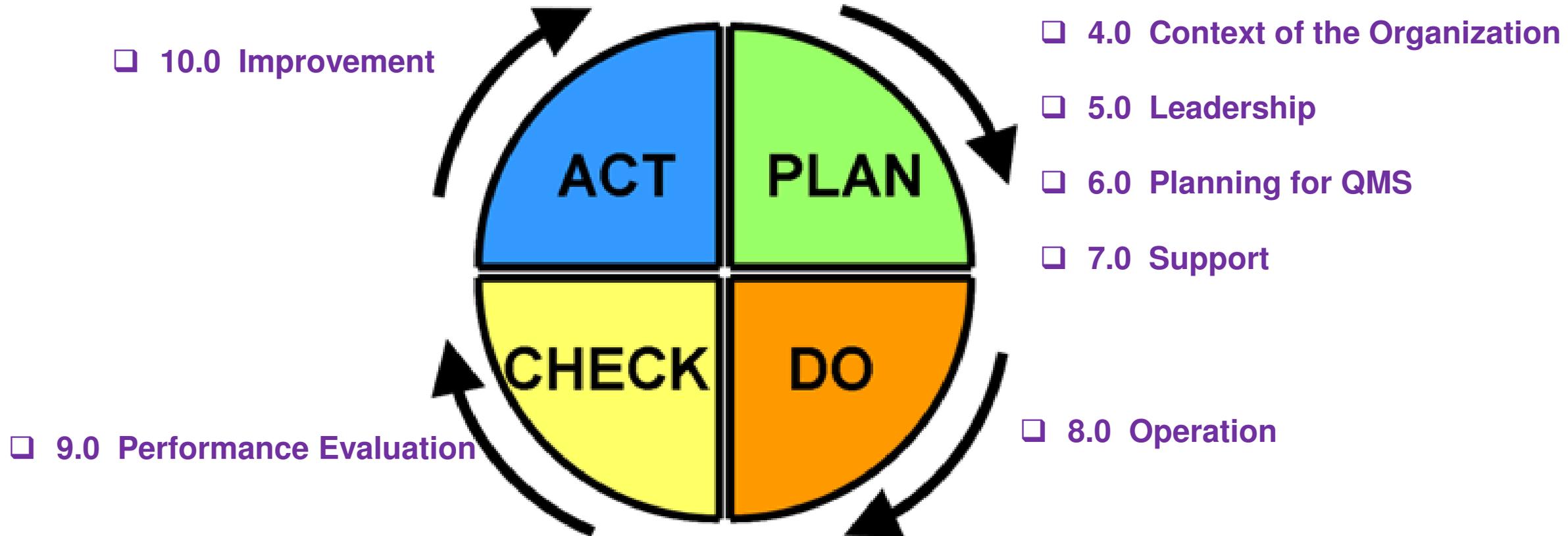
# Process approach



## Typical Processes

1. Recruitment Process
2. Break-down Maintenance
3. Calibration Process
4. Materials Planning process
5. Production process
6. In-process Inspection process
7. Storing of FG & Despatch Process
8. Tool Design Process
9. Reliability Testing Process
10. NPD Process

# ISO 9001:2015 Main clauses vs PDCA cycle



# CLAUSES OF ISO 9001 : 2015

## 1 Scope

## 2 Normative Reference

## 3 Terms & Definition

## 4 Context of the Organization

*Basic understanding about the Organization, Expectations of the Interested parties, Scope of QMS, Processes of QMS*

## 5 Leadership

*Commitment by the Top management for QMS implementation, Policy, Customer focus, Roles, Responsibilities and Authorities*

## 6 Planning for QMS

*Risks & opportunities, Objectives, Changes to QMS*

## 7 Support

*People, Infrastructure, Process Environment, Monitoring & Measuring resources, Knowledge, Competence, Awareness, Communication, Documented information – creation, updating & control*

# 10 ( Sub clauses not included ) Main Clauses

## 8 Operation

*Planning & Control, Determining the requirements for Products & Services, Design & development, Control of externally provided products & services, Production & Service provision, Release of Products & Services, Control of Non-conforming products & services*

## 9 Performance Evaluation

*Monitoring, Measuring, Analysing & Evaluating, Internal audit, Management Review*

## 10 Improvement

*Non-conformity & Corrective action, Continual improvement*

# Team Based Exercise

Ex # 7



## Type of Exercise :

- Situation Analysis
- Choose the best Answer
- Word Puzzle
- Matching of terms
- Mapping & GD

## Focus

- ❖ Recap the Learning so far
- ❖ Distribute the Sheet
- ❖ Answers in the next slide !



Your Team Ref : .....

Date : .....

**Match the following in a Most Logical way w r t the  
ISO 9001-2015 Standard !**

<b>Alphabets</b>	<b>Terms</b>	<b>Numbers</b>	<b>Terms</b>	<b>Your response</b>	<b>Evaluation</b>
A	ISO 9001 – 2015 Latest version	1	Seven by numbers		
B	Requirement ( 3.03 )	2	3 years period maximum		
C	Management Principles	3	ISO 9000 standard		
D	Quality Policy of the Organization	4	Changes in the 5 <sup>th</sup> Edition		
E	Fundamentals & Vocabulary	5	Process to determine a value		
F	Measurement ( 3.16 )	6	Geneva		
G	ISO 19011	7	Suppliers & Dealers		
H	Switching over to the new Standard	8	Clause 5.2		
I	ISO Head Quarters	9	Stated, Implied & Obligatory		
J	QMS Standard ISO 9001:2015	10	For Auditing purpose		
K	Interested Parties	11	5 <sup>th</sup> Edition		
L	Process Approach & Risk management	12	A Process Standard, Not product		



# Requirements

- Understanding the Requirements !
- Understanding the Background well !
- Designing the QMS Procedures
- Implementing the QMS Procedures

↑  
" Maintain & Improve "

**Accelerated**

# Learning Process



- Please go through the Standard along with your team !
- Try yourself to update the contents given in the Course material !
- We are here to help you, as needed !



- 4.0 Context of the Organization**
- 5.0 Leadership**
- 6.0 Planning for QMS**
- 7.0 Support**
- 8.0 Operation**
- 9.0 Performance Evaluation**
- 10.0 Improvement**



*Self-Evaluation!*

*Please decide only based on the Standard!*

Clause #	Clause Description
4.0	Context of the Organization

#	Statement	True	False	Review
1	Scope of the Organization to be available as a Documented information			
2	Customer is also one of the Interested Parties			
3	Statutory & Regulatory requirements are known as Legal requirements			
4	Scope shall be defined by QA department only			
5	When there is a change in the Scope, the document shall be amended for the change			
6	Scope covers only Products not Service of the Organization			
7	One tool used for defining the QMS processes is Turtle Diagram			
8	QMS processes to consider both Risks & Opportunities			
9	Turtle diagram must consider only important Processes of the Organization not all processes			
10	Process Approach is to be mapped for all the Processes & also for their Interactions			

**For the ...**

- ✓ Engineers
- ✓ Executives
- ✓ Managers

**of ANY department !**

More & more Exercises !

Very much Practical in Approach !

Highly Interactive !

Let's get prepared to welcome the new Standard with confidence !

**Please Contact**

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