

Preparatory Program on

ISO 9001 : 2015

Quality Management System

Edition #
5



Q M S

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 :

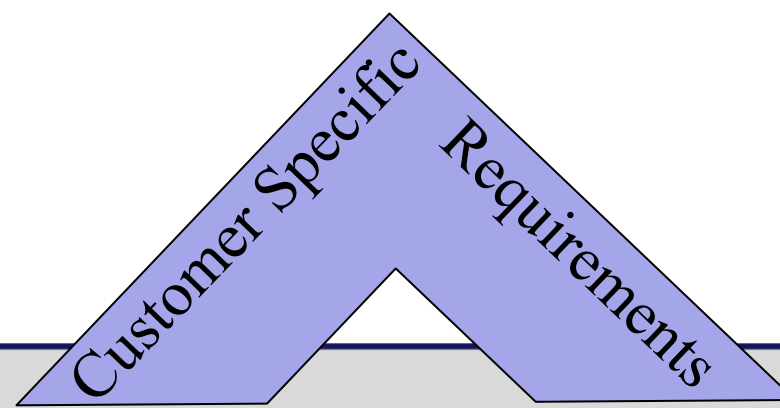
- » Class Room Lecture
- » Brain storming on requirements
- » Situations analysis
- » Group Presentation
- » Accelerated learning
- » Idea building through G D
- » Examples for QMS documentation

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



ISO / TS 16949 Requirements

ISO 9001 Requirements



Management Principles

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



#	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		

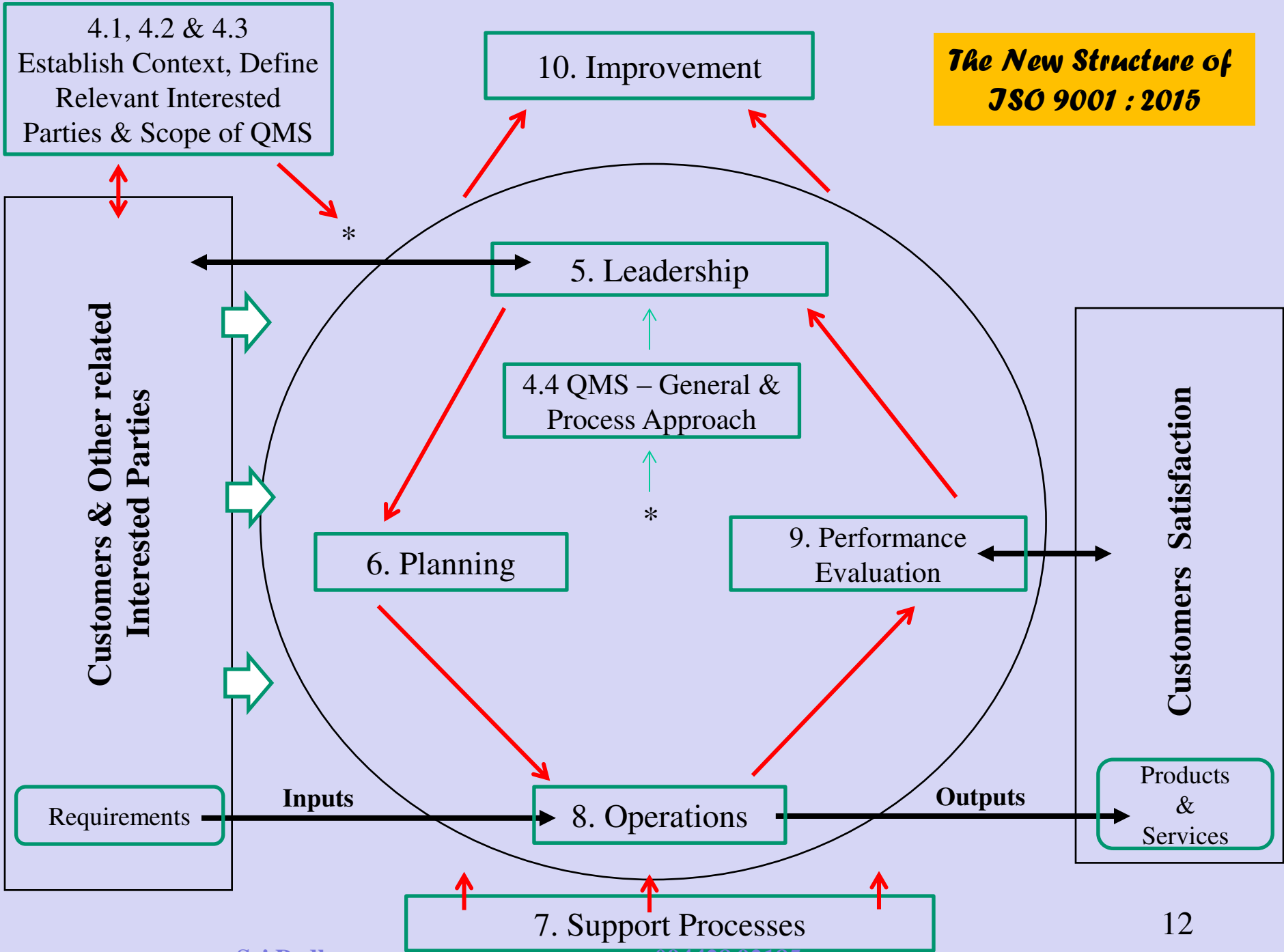
#	Question / Statement	Your Response	Evaluation
6	Opportunities are generally related to the - a) Risks involved in them b) Objectives set already c) None of the above		
7	QMS documentation is part of - a) 'Plan' element. b) 'Act' element. c) None of the above		
8	In every Failures - a) Risk levels will 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





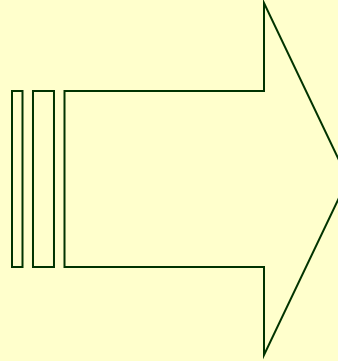
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Quality Management Principles

- ☐ *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



Requirements



Stated

Implied

Obligatory

Changes in the Terms in 5th Edition

#	ISO 9001 : 2008 (4 th Edition)	ISO 9001 : 2015 (5 th Edition)
1	Products	<i>Products & 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 & Process</i>
5	Purchased Product	<i>Externally provided Products & Services</i>
6	Supplier	<i>External Provider</i>

Process approach



What ?

Why ?

How ?

Section 0.3 of QMS

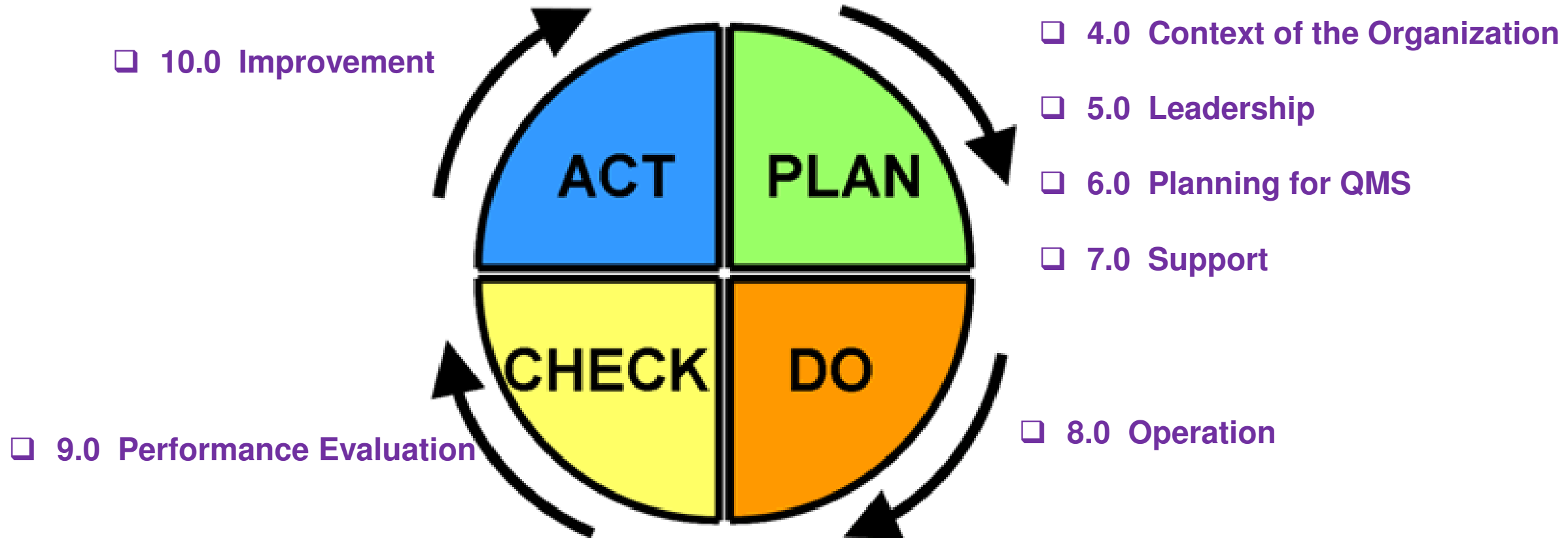
Process approach



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 !**

Alphabets	Terms	Numbers	Terms	Your response 	Evaluation
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 th 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 th 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



Clause #	Clause Description
4.0	Context of the Organization

*Self- Evaluation !
Please decide only based on the Standard !*

#	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
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