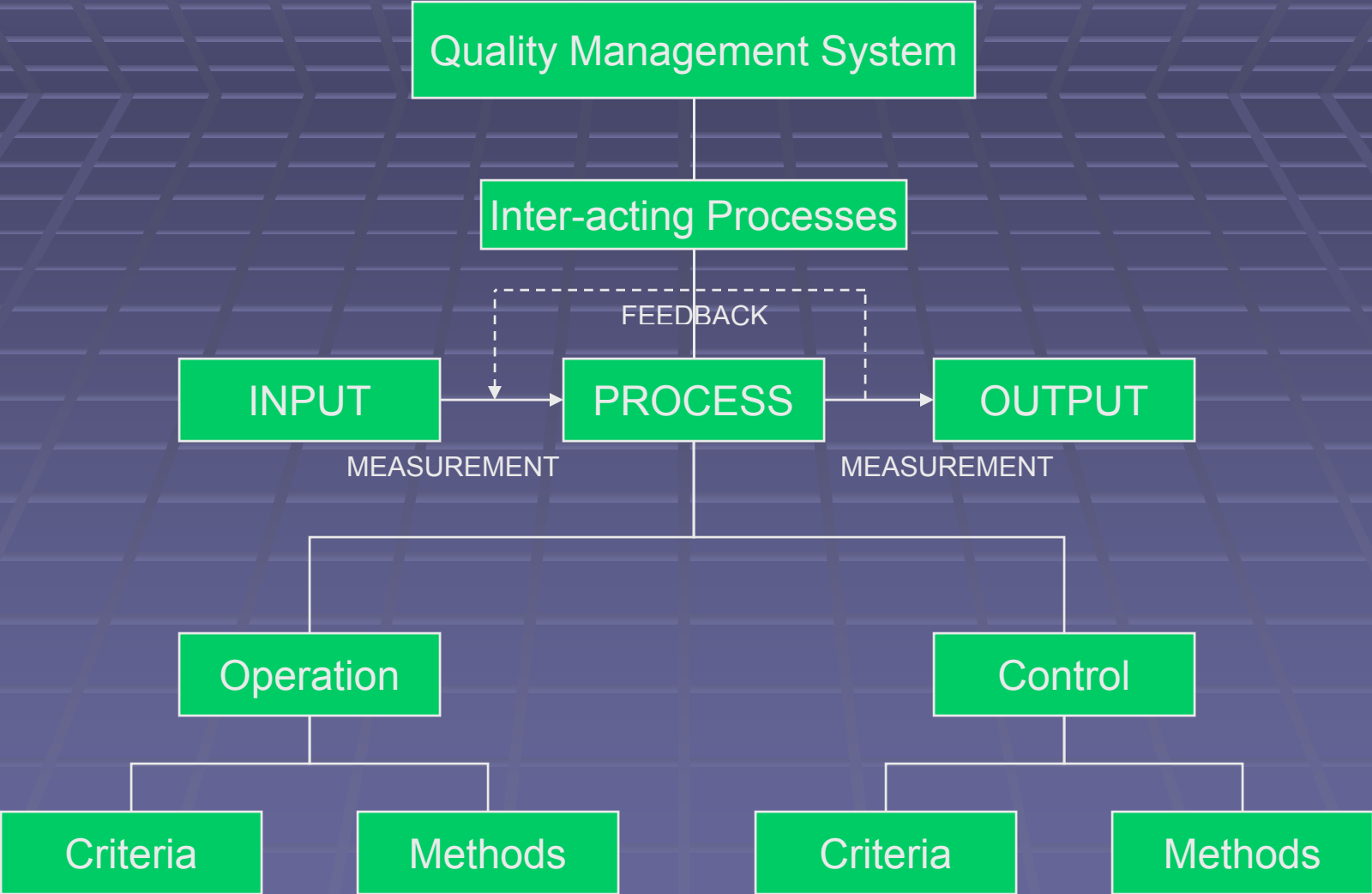


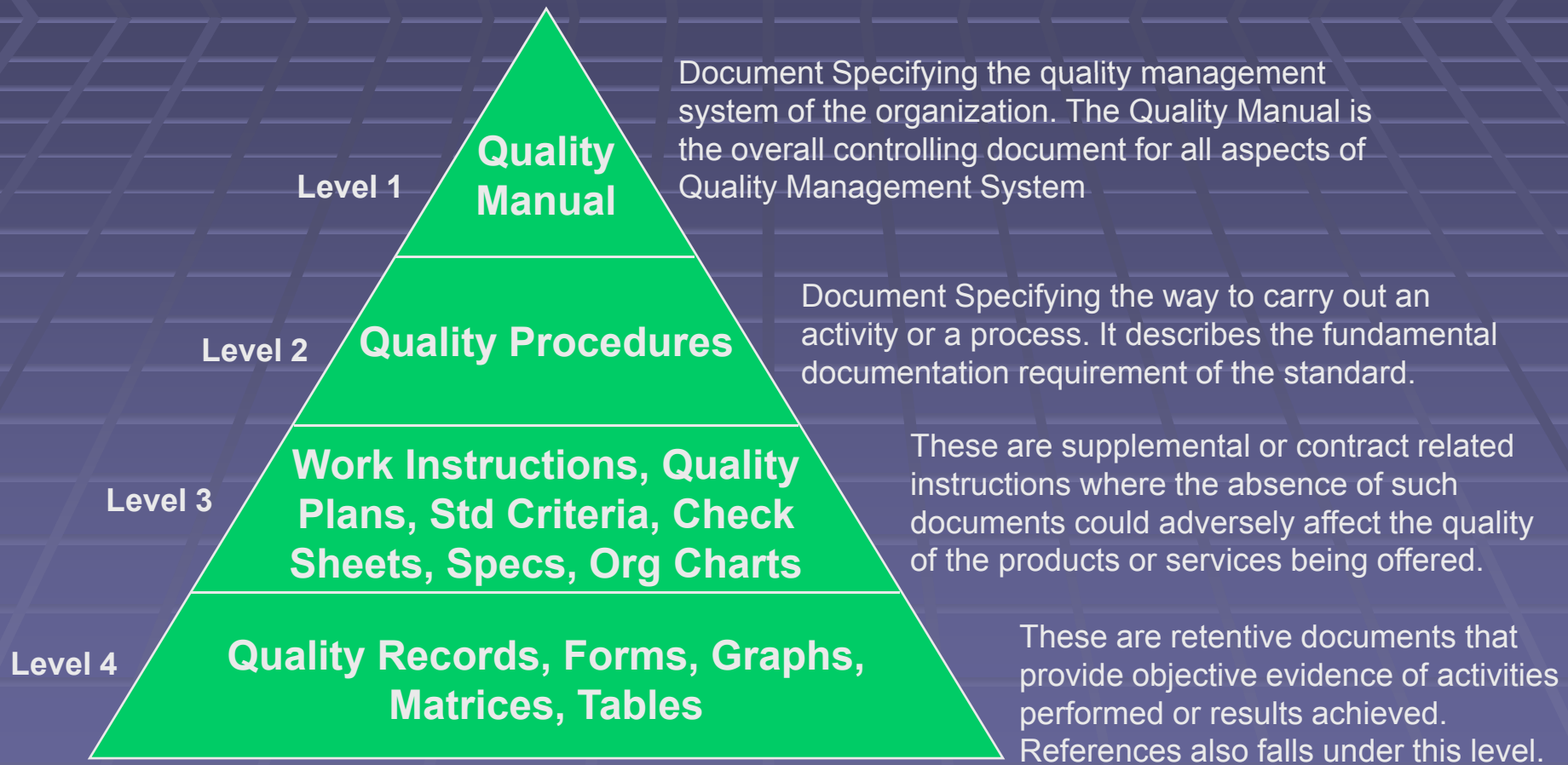
# ISO 9001:2000 Standard Requirements

Topic II. Summary of  
Requirements

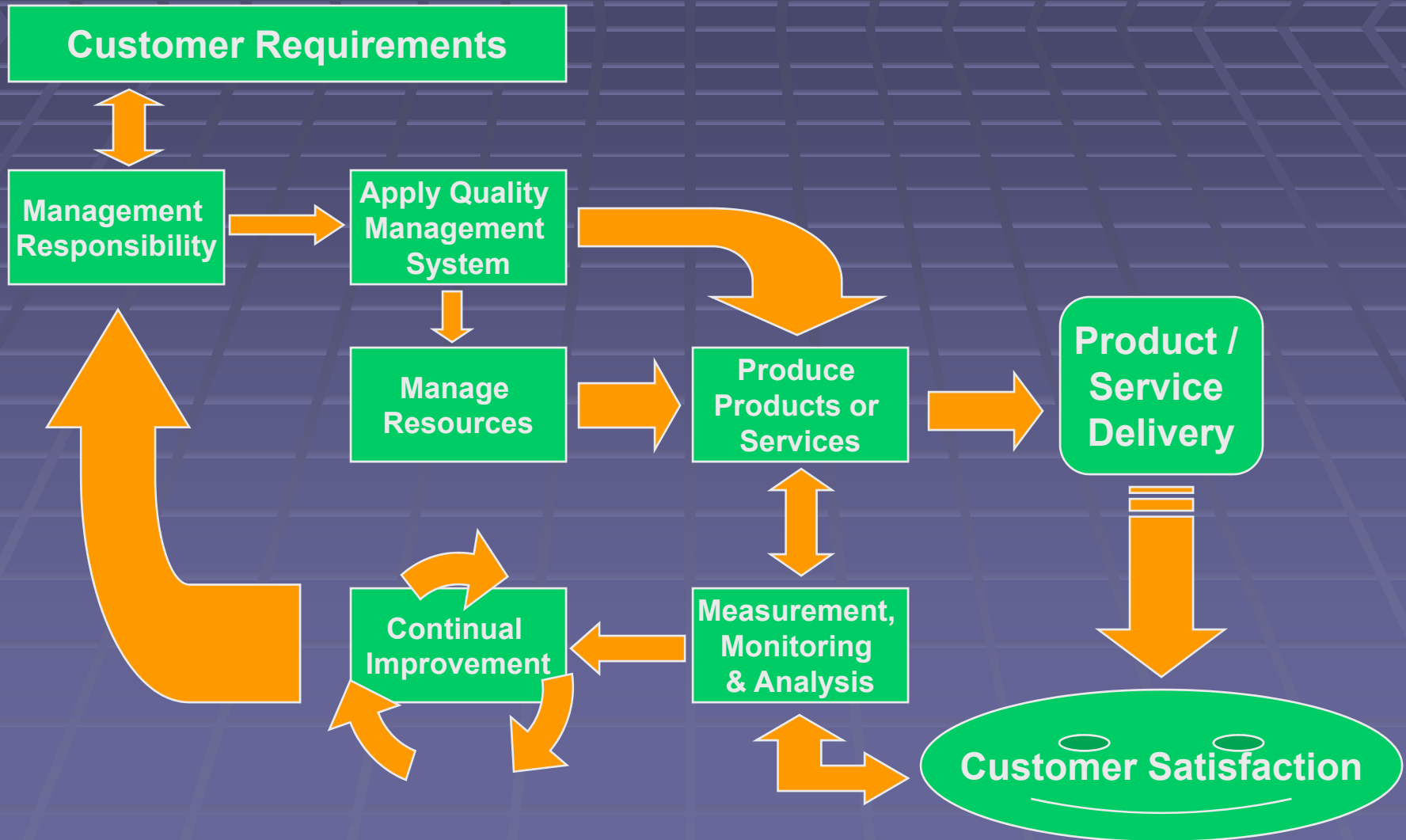
# Quality Management System Structure



# Documentation Structure & Hierarchy



# Business Process Model ISO 9001:2000



# A Brief Overview

- ISO 9001 is a very simple Standard to understand: PREVENTION
- Sections 1,2,3 of the standard are simply ‘introductory’ text and do not impact the fulfillment of the requirements
- Sections 4,5,6,7,8 contain the requirements that MUST be applied – if appropriate to the company’s scope of work and contractual relationship with customers. The word “Shall” is used throughout the standard and it is mandatory
- Information marked “NOTE” is for guidance and understanding or clarifying requirements.

# Requirements Summary

Total Number of 'Shall'  
(Mandatory Requirements) = 135

Total Number of Notes = 13

Total Number of Clauses = 51

# ISO 9001 Requirements Table

FUNCTION DESCRIPTION	Percent Contribution on Meeting Requirements:	
	Per Clause	Per Shall
Top Management	<b>11/51 = 22 %</b>	<b>16/135 = 12 %</b>
Quality Management Representative (QMR)	<b>4/51 = 8 %</b>	<b>9/135 = 7 %</b>
Sales and Marketing	<b>5/51 = 10 %</b>	<b>12/135 = 9 %</b>
Quality Management (QM)	<b>9/51 = 18 %</b>	<b>29/135 = 21 %</b>
Quality Assurance/Quality Control (QA/QC)	<b>3.5/51 = 7 %</b>	<b>14/135 = 10 %</b>
Production (Operation)	<b>3/51 = 6 %</b>	<b>9/135 = 7 %</b>
Facilities and Maintenance	<b>2/51 = 4 %</b>	<b>9/135 = 7 %</b>
Warehouse	<b>2/51 = 4 %</b>	<b>6/135 = 4 %</b>
Human Resource and Administration	<b>2/51 = 4 %</b>	<b>2/135 = 1.5 %</b>
Purchasing	<b>2/51 = 4 %</b>	<b>7/135 = 5 %</b>
Engineering/R&D	<b>7/51 = 14 %</b>	<b>23/135 = 17 %</b>
Production Planning and Inventory Control	<b>0.5/51 = 1 %</b>	<b>1/135 = 0.75 %</b>

## Remarks:

Functions may vary from one organization to another due to the size and nature of business. For presentation purposes these functions were applied due to familiarity.