

ISO13485:2003

ISO9000:2000	The standards most companies comply with
EN46001	Needed for CE marking to the Medical Directive

Comprises

Statement of Intent : In the Kitchen.

Company Policy Statement and Objectives

Viamed Ltd is totally committed to achieving the highest levels of Quality in all the products we supply and the services we provide. Therefore if we are to succeed, all our employees must share this objective too.

Our Customers judge us by our products and services, therefore we must be totally committed in our outlook with regards to Quality.

One of our Business objectives is to continually meet the requirements of the various international systems to which we have been assessed and approved. Conformance to the Processes and Systems recorded in this Quality Manual is mandatory, and will enable us to meet that objective.

In addition to strict adherence to these processes we need to continually develop and maintain the right Attitude towards high Quality achievement throughout the company.

Only in this way will we reach our Quality Policy of complete customer satisfaction .

Quality manual : Says what we intend to do to comply with the Standard.

Procedures: Says how we will do it

<i>Section</i>	<i>Procedure</i>	<i>Title</i>	<i>Charts</i>
1	#01	Company Documentation	1, 10, Interfaces
2	#02	Personnel Responsibilities	1, 2
3	#03	Office Process	3, 13, 29
4	#04	Vigilance	8, 26, 27
5	#05	Supplier Control	11, 15
6	#06	Measurement Control	7, 20, 21, 25
7	#07	Stock Control	11, 15, 20, 21, 22, 23, 24, 25
8	#08	Production	6, 20, 28
9	#09	Repairs	6, 21, 28
10	#10	Corrective & Preventive Actions	8, 27, 28
11	#11	Equipment Control	18, 28
12	#12	Human Resources	2, 9, 11
13	#13	Process Monitoring	7, 16, 19, 26
14	#14	Servicing	3, 21
15	#15	Data & Information Analysis	1, 7, 8, 9, 16, 19, 26, 27, 28
16	#16	Health & Safety	1, 7, 8, 12, 19, 26
17	#17	R & D	4, 5, 10, 17,
18	#18	Maintenance & Environmental	2, 11, 12

Important we as a company know ISO 13485 and all its clauses.

The Quality manual covers every clause

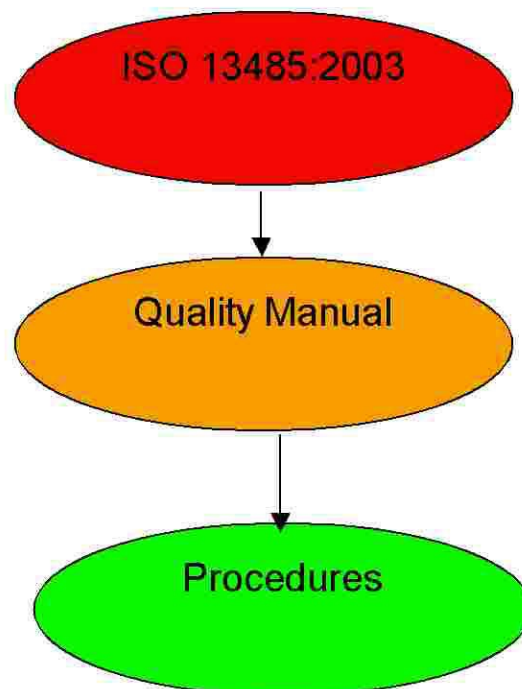
The procedures must be followed 100%.

If we change the procedure: e.g. Updated electronic systems etc. we need to change the written procedure.

We then must record the change.

ISO 13485:2003

Structure

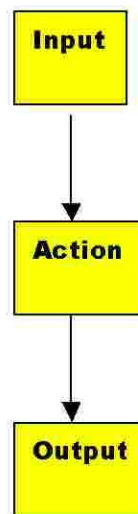


What's different from our original ISO

ISO13485 is a process based system

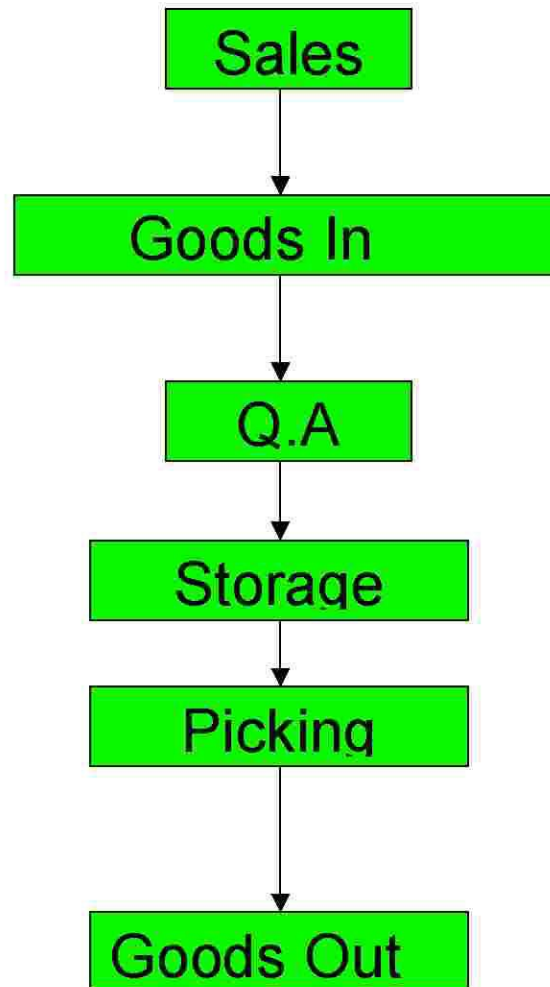
ISO 9000 was a procedure based system

What is a process



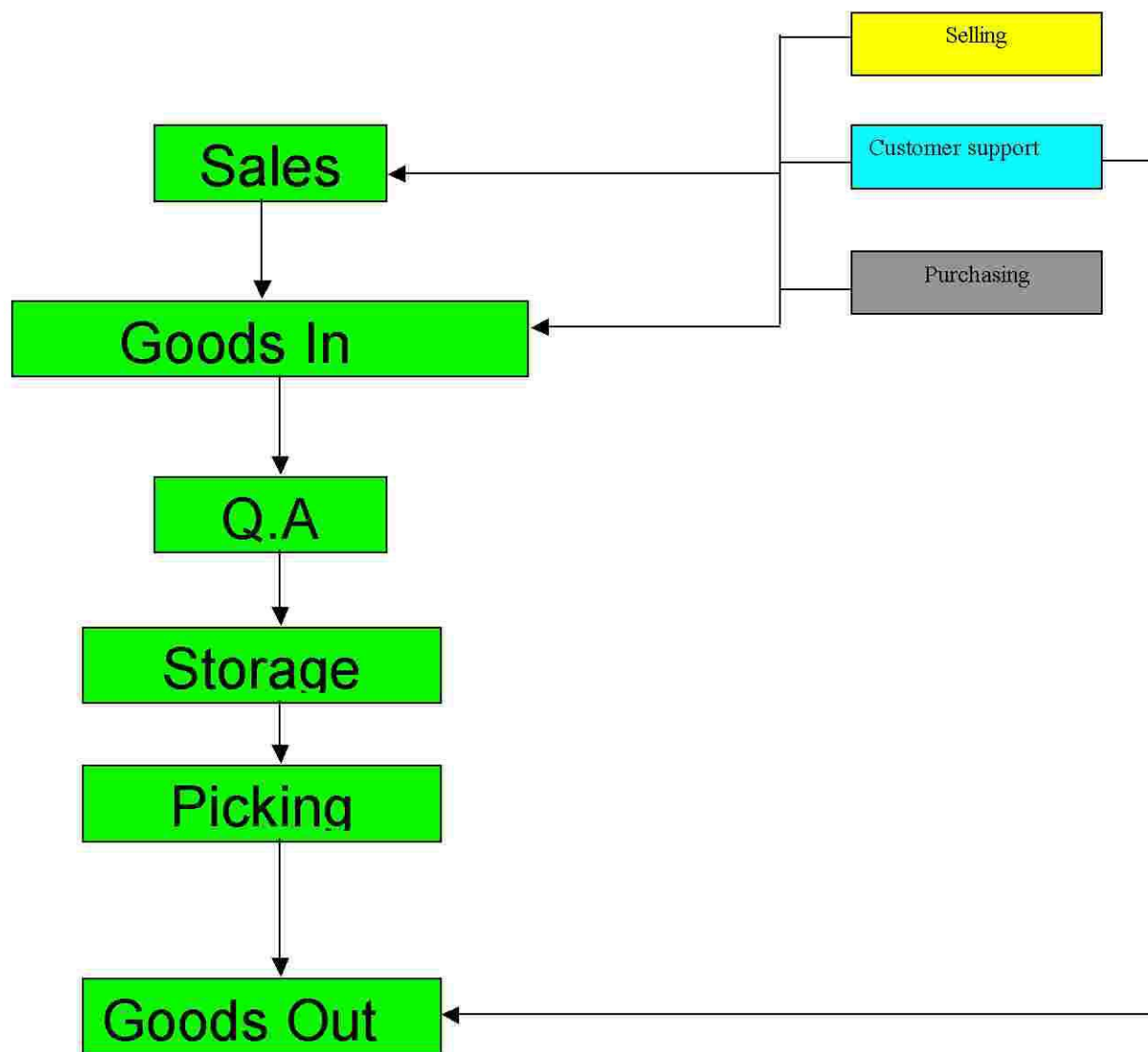
We can measure
Record
Evaluate

Viamed processes

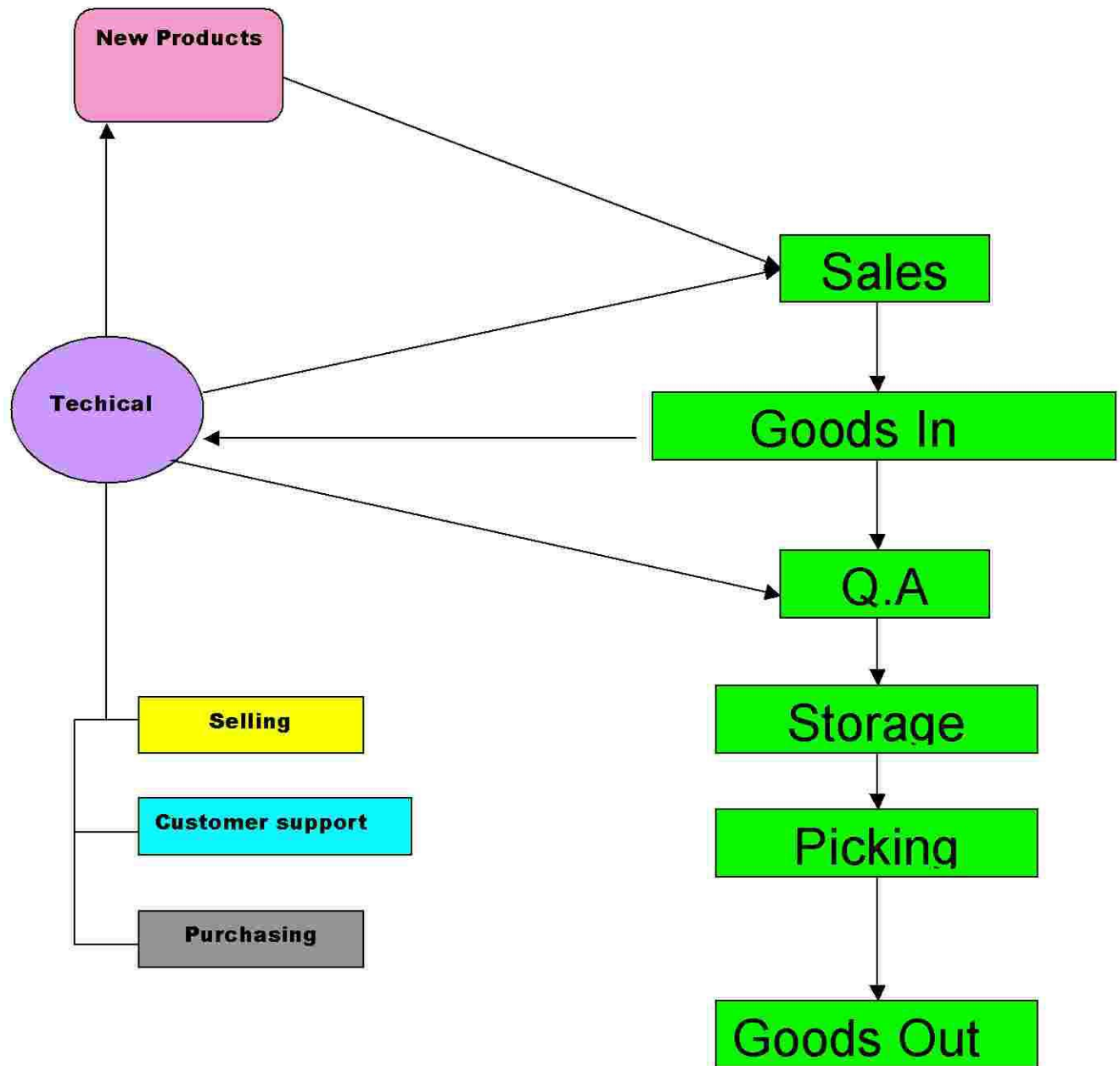


This is only one of many processes

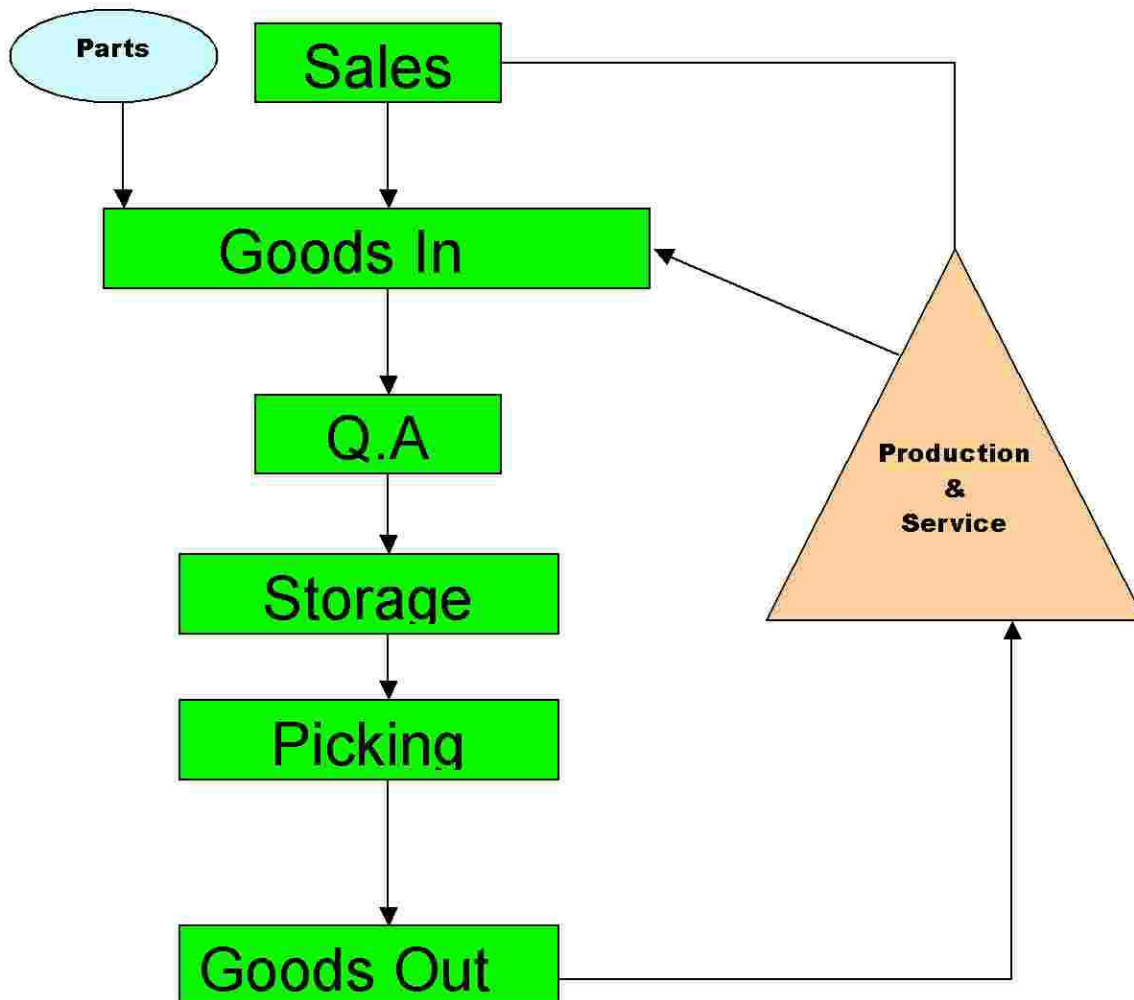
They all interact
They do not stand-alone



Technical



Production & Service



Conclusion

**The whole company is governed by
ISO**

Everyone is part of ISO

Everyone is responsible for ISO

**The strength of ISO is
the**

Weakest Link

Teamwork