

Quality Manual

ISO 9001 - 2008
NF EN ISO 13485 - 2004
Directive 93/42/CEE



Revision 14

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Approved by	F. ORY	General Manager	FO 13/02/2011

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Chapter 1 : Introduction

Scope

This Quality Manual (MQ) introduces the conditions of operation at VBM in order to obtain, master, make sure that quality objectives are met according to :

- Customers' requirements,
- Requirements of the Quality Management System (QMS) in the framework of the ISO 9001:2008,
- Special requirements to specific features of medical devices (GM) under the norm NF-EN ISO 13485 :2004,
- Directive 93/42/CEE : 2008 related to medical devices.

As well as improving customer satisfaction & develop a continuous improvement behaviour.

The MQ is made available to all VBM & related personal, under the supervision of the Quality Manager (MQ)

The QM 's responsibility is to introduce and explain the content to any new VBM & related personal .

Exclusion

VBM 's objective is to remain a sub-contractor to the MD industry : therefore the Chapters Design & Developments from the norms l'EN 13485 (2004) and ISO 9001 : 2008 are excluded.

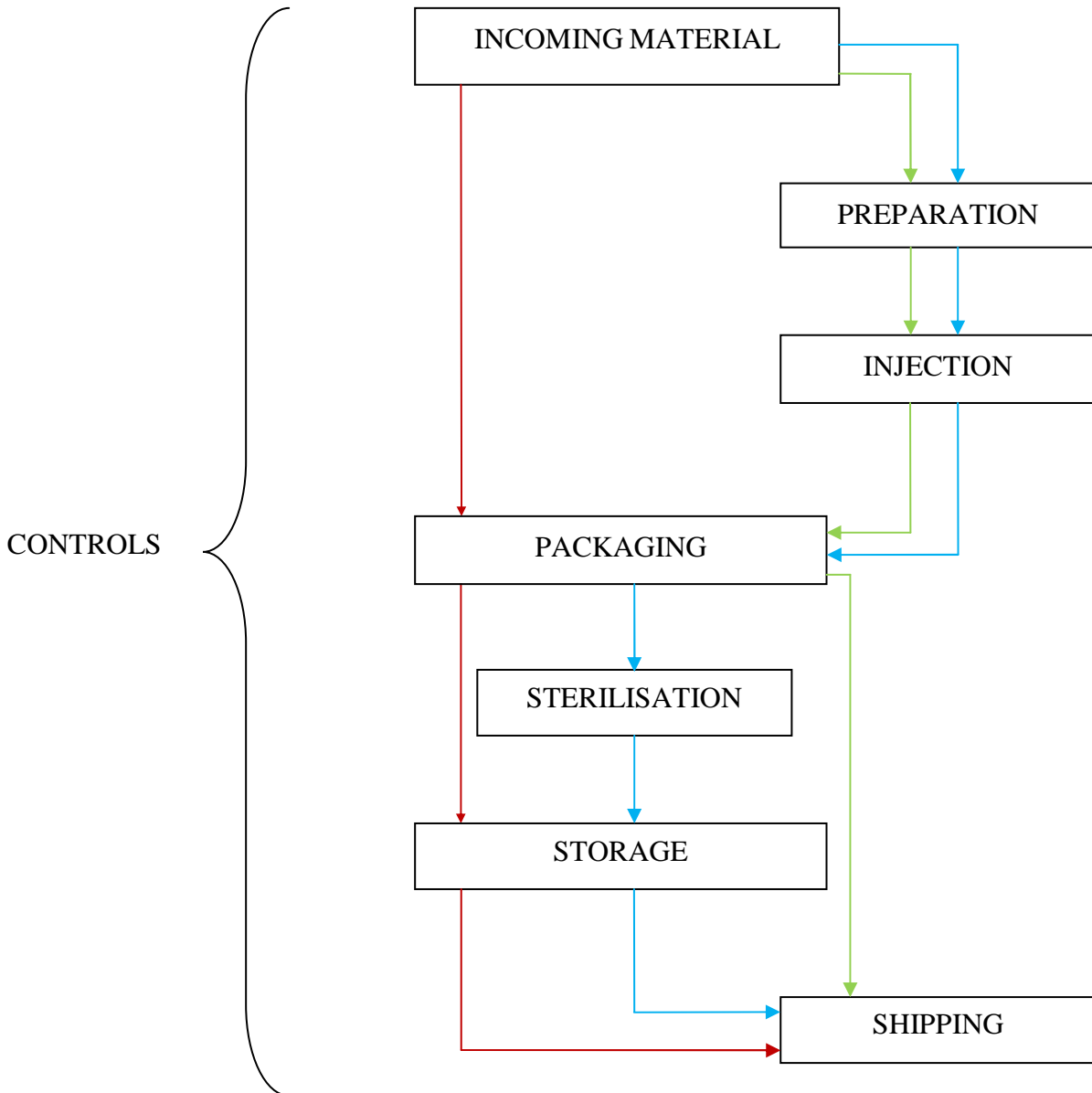
<u>Abréviations</u>	
AAC : Accounting Assistant	PR : Procedure
BL : Delivery note	RAF : Admin & Finance Manager
CDC : Specification	RC : Sales Manager
F : Form	RDD : Management Review
IQE : External Quality	R&D : Research & Development
MO : Operating	RP : Production Manager
MQ : Quality Manual	RQ : Quality Manager
NC : Non-conformity	SC : Sales Department
OP : Injection press operator	SMQ : Quality Management System

Chapter 2 : Presentation

<u>Name</u>	VBM Sarl
<u>Brand</u>	VBM Orthopaedic Polymers
<u>Address</u>	Campus industriel de la Brande Chemin de St- Amand 03600 MALICORNE FRANCE
<u>Tel</u>	+33 (0) 4 70 09 78 20
<u>Fax</u>	+33 (0) 4 70 09 78 21
<u>Legal Incorporation</u>	LLC with 50.000 € in equity
<u>Created</u>	Septembre 1998
<u>Staff</u>	2
<u>Business</u>	Injection moulding of polymers for use as medical devices & distribution of biomaterials

Manufacturing

Own products
Trading Distribution
Contract Manufacturing



Chapter 3 : Commitment from the Management

3.1 General Manager commitment.

Quality, extended to all services, departments .. must be everyone's focus.

Quality is everyday, in every step we undertake, for each and everyone of us. With 12 years in operation, VBM has developed quality and seriousness with the objective of :

Customer satisfaction , regulatory compliance and continuous improvement

Quality behaviour means to help develop VBM:

- On its markets, because the survival & development can only be insured with loyal customers as well as new customers.
- in its P&L, because only a fair profit margin can allocate wealth for new investments, retribution to employees and to its parent company.,
- In its internal relations, because projects can be achieved only thru team work, adequate communication, constant effort in information & training ,
- In its outside relations, because, in order to grow, we need active support from our customers, suppliers, contractors considered as partners,
- In its environnement, natural or social, in our legal framework and the understanding of the environmental & sustainable challenges ahead of us..

I request all personal, whatever their jobs are, to constantly act in the respect of our common goal, to report any problem in order to find a solution for the sole customer satisfaction, again within the framework of our business, and the values shared in our organization.

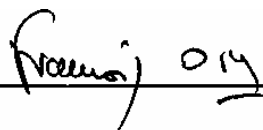
I will make sure to support this action with material & human resources that are necessary to the implementation of this policy .

To live this quality, I will personally handle Quality Management to guarantee the efficiency of the system..

However, to help implement this policy, a position of External Quality Advisor is created to bring energy on a regular basis to achieve this goal.

The independence, the autonomy and responsibility to conduct this mission are clearly designated..

07 february 2011,



François ORY
General Manager

3.3 Quality Policy

The policy, described in this document, is applicable to all activities of VBM.

To best work in the spirit of the Norms, we have taken a decision to implement a Process approach that best fits our organization.

We start from the customer's demand to aim at its satisfaction. This approach provides the skeleton of our organization with Processes (see Mapping) and a Pilot..

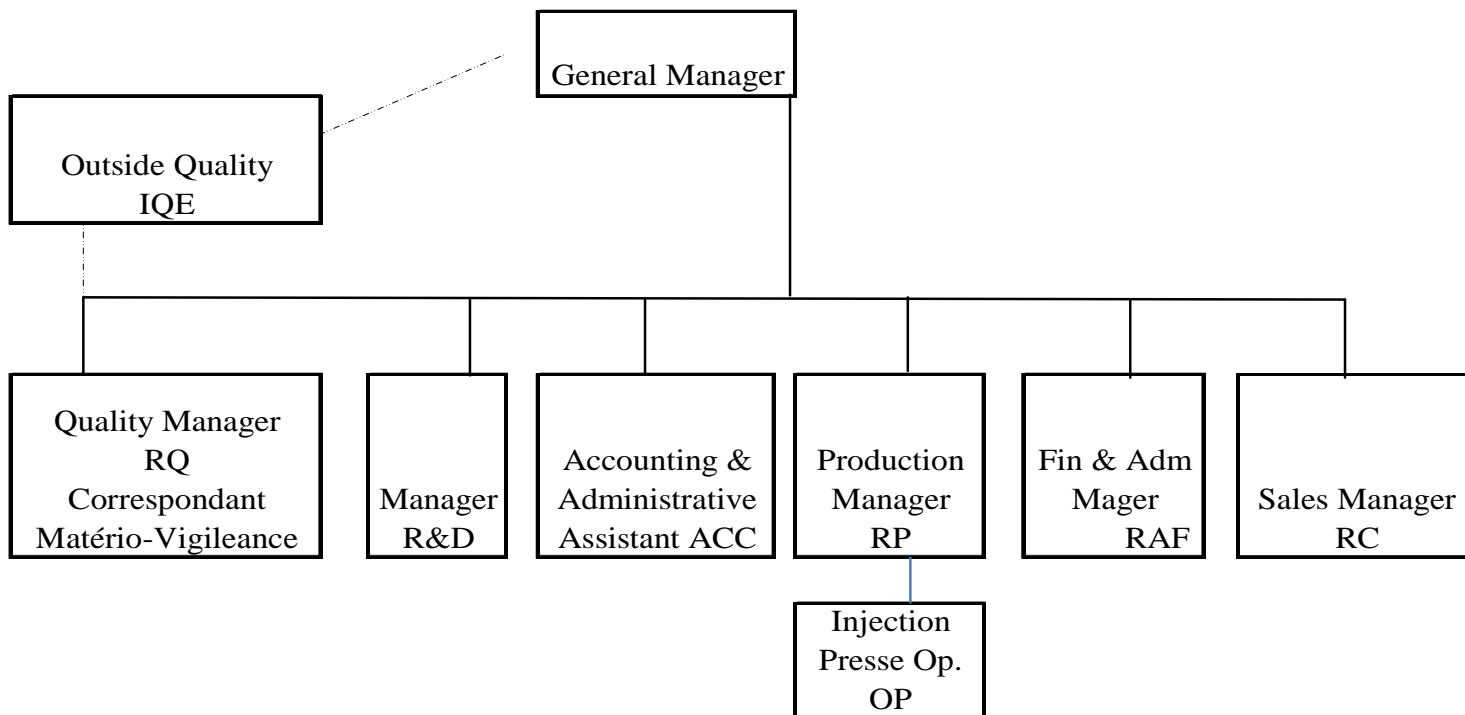
For each and every Process, a Pilot has described : goal, input data, output data, the logical details and interaction with other processes. Set indicators then help measure the efficiency of the Process.

The QM leads the Risk Management Review and reports its findings.

Thru Internal & External Audits, as well as Management Reviews, management checks its quality policy in relation with the results versus the set objectives.

During Management Reviews, Management checks and make sure that each Pilot has planned actions related to its objectives, sets new objectives for the period to come, while allocating appropriate resources.

3.4 Responsibility et authority

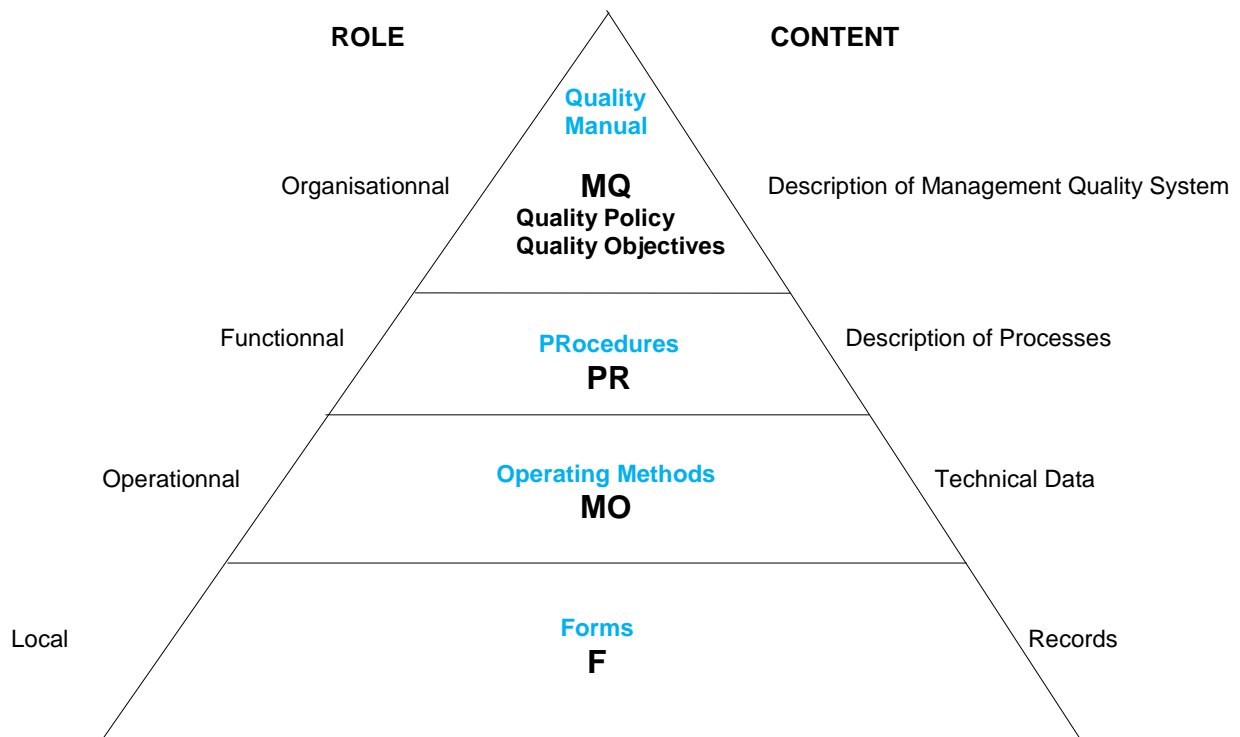


The above graph describes the hierarchy of VBM. Jobs, functions listed above are explained in further details in documents MO/01-01 to MO/01-07 « Job description ».

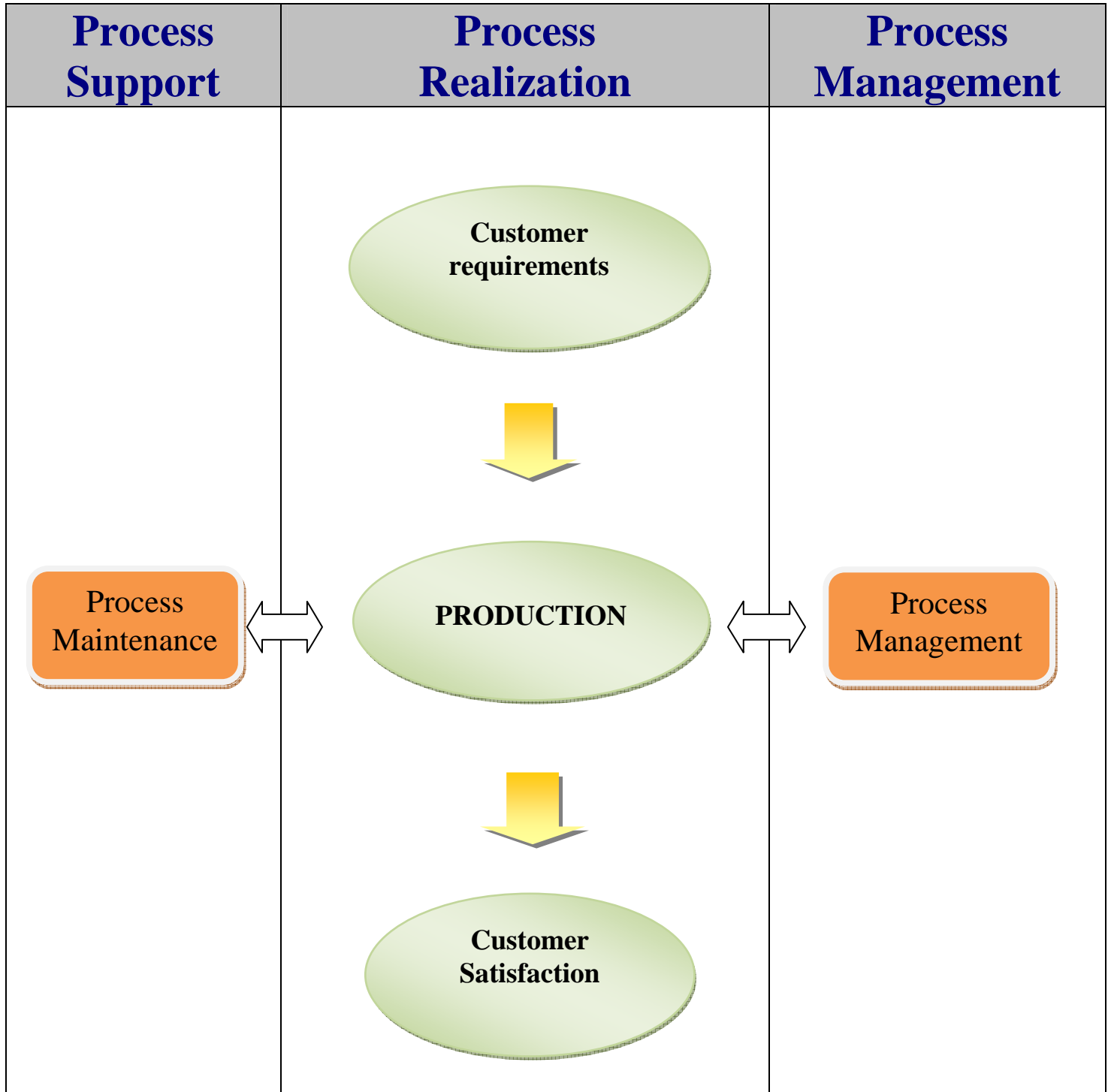
The General Manager sets the objectives, in term of quality, sales, P&L, administrative & production. His main task is to convey those objectives and to underline the importance of customer satisfaction..

3.5 Architecture

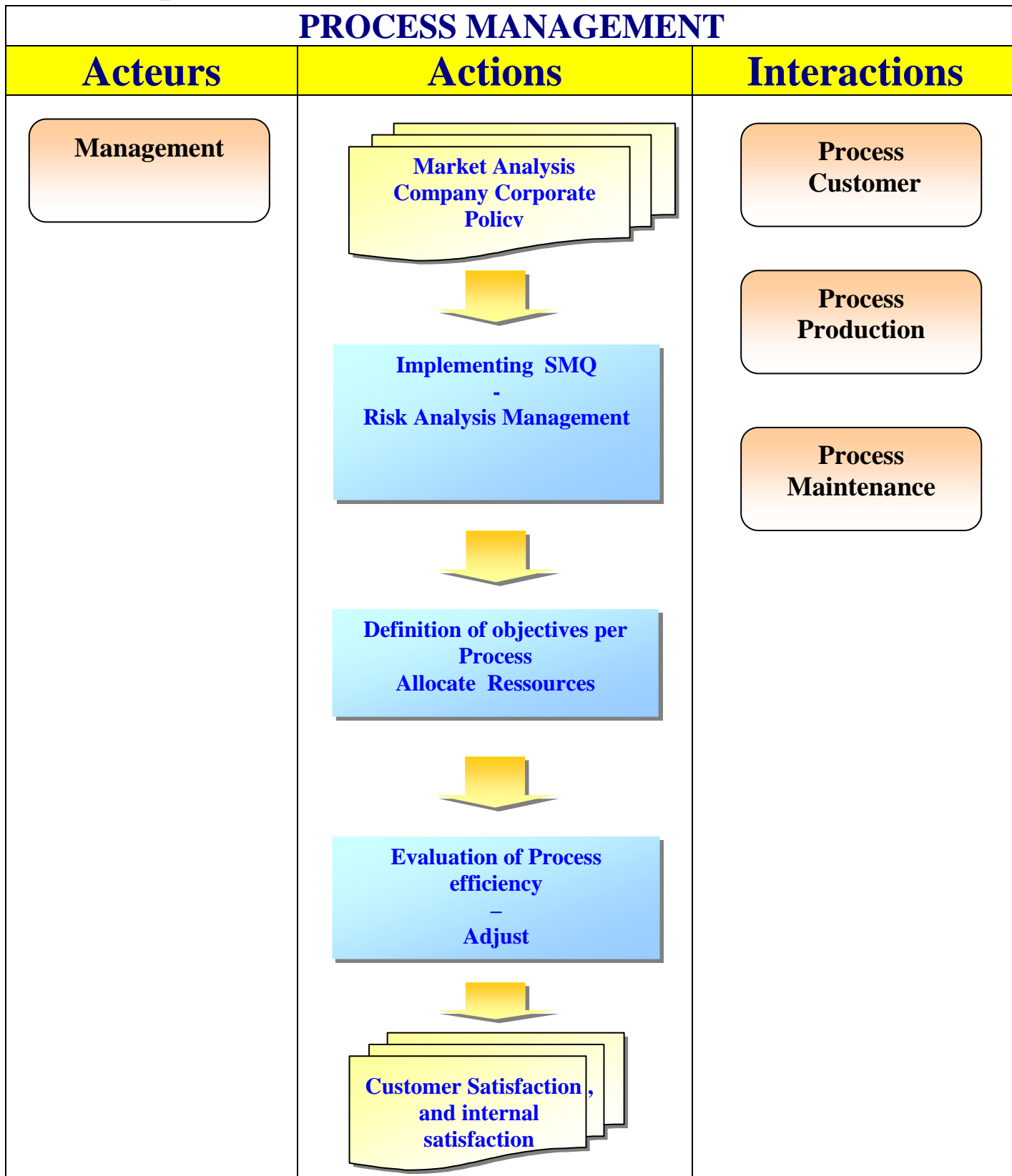
SMQ & resources



Chapter 4 : Processes Mapping



Chapter 5 : Process et Indicators



Process : Management

Pilote : Management

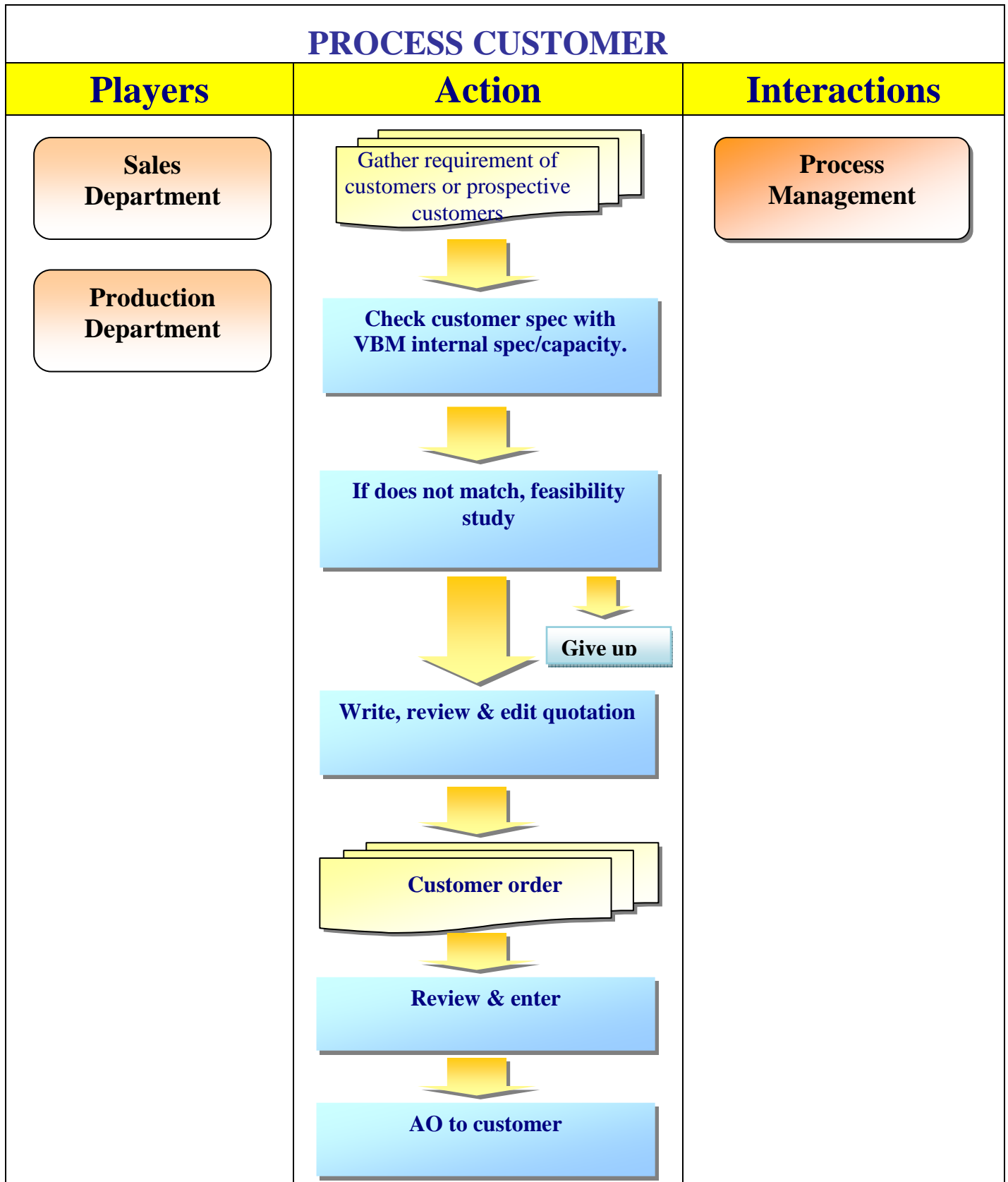
1 - Definition :

Define, plan & control the corporate policy.

2 - Indicator / Source / Person in Charge :

Indicator(s)	Source	Person in Charge	Frequency
Sales	Monthly Report Table	AAC	Monthly
Ebitda	P&L and Balance Sheet or end of period interim status.	RAF	Half Year

PROCESS CUSTOMER



Process: Customer

Pilot: Management

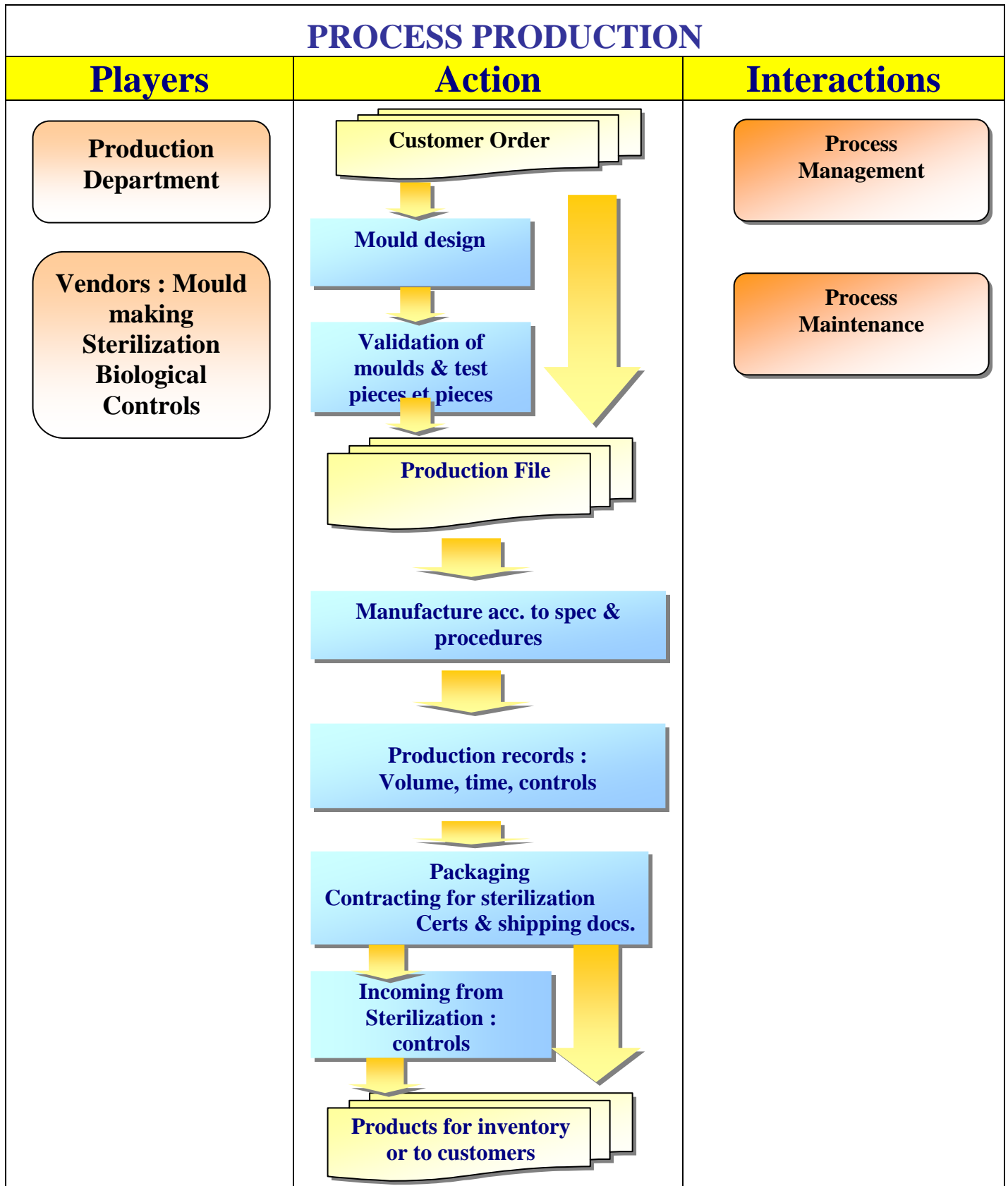
1 - Definition:

Taking into account actual & new requirements from the customers

2 - Indicator / Source / Person in Charge :

Indicator (s)	Source	Person in Charge	Frequency
New customers on yearly period	Table of Customers	AAC	Yearly
Customer loyalty (80% compared to preceding year)	Table of Sales Customers/monthly report	AAC	Quarterly

PROCESS PRODUCTION



Process : Production

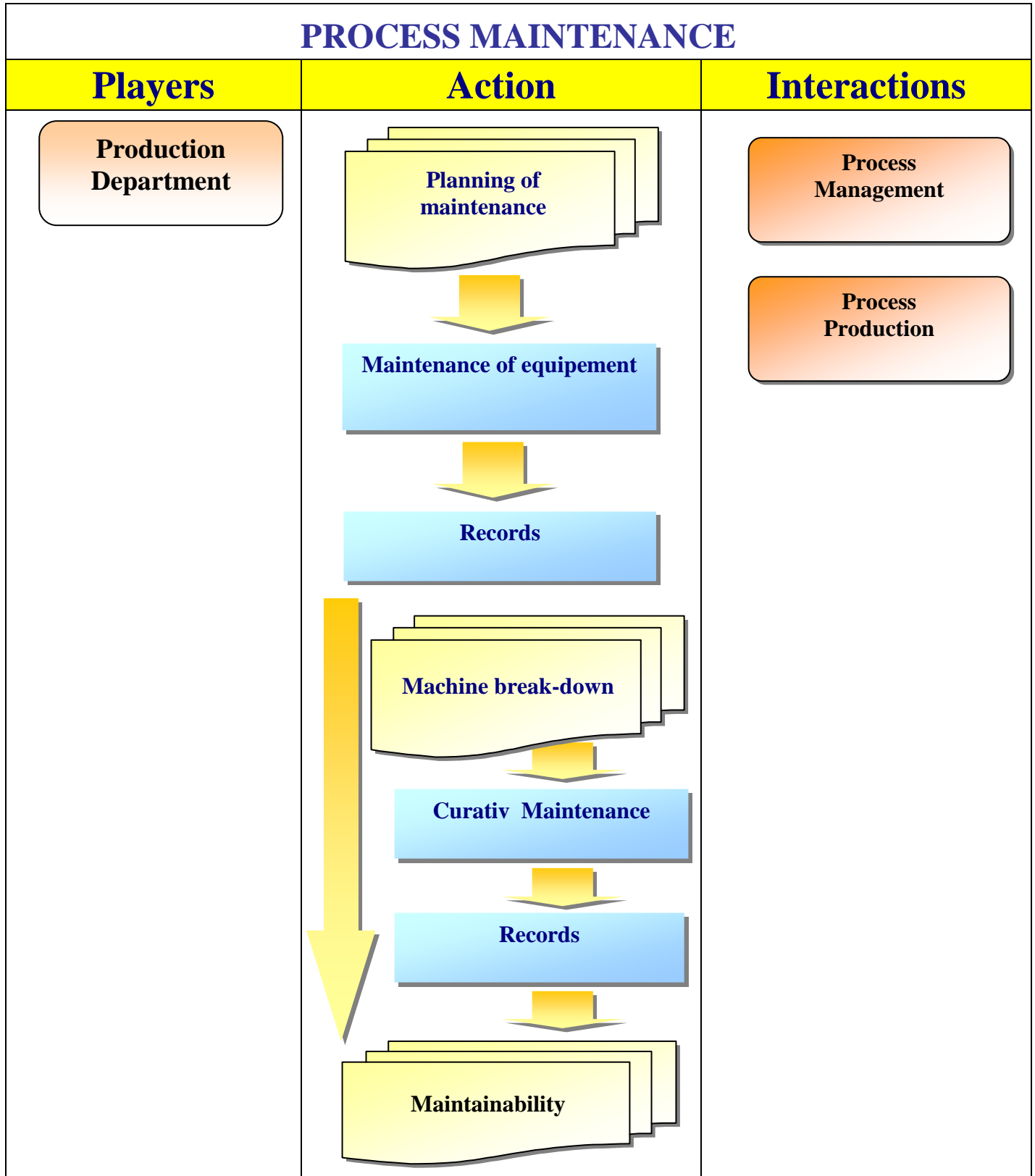
Pilot: Production Manager (RP)

1 - Definition:

Organize production, from incoming order to product final availability.

2 - Indicator / Source / Person in Charge :

Indicator(s)	Source	Person in Charge	Frequency
Meeting delivery deadlines	Late delivery file access	RP	Monthly
Level of Claim	Non conforming report F13-01	RP	Half year
Yield Reality (actual use of material /actual good to process)	Real Yield Excell file	RP	Monthly
Yield Theoretical (actual use of material/estimated quantity)	Thearetical Yield Excell File	RP	Monthly



Process : Maintenance

Pilot: Production Manager

1 - Definition:

Manage preventive & cutativ maintenance

2 – Indicator / Source / Person in Charge

Indicator(s)	Source	Person in Charge	Frequency
Meeting deadlines of planned maintenance.	Maintenance File F09-10	RP	Half Year

<p>Appendix 1 POSITIONS HELD AT VBM ORTHO POLYMERS</p>
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Refer to Chapter 3 of QM :

General Manager.....	F. ORY
Manager R&D.....	J.C.MENARDIE
Production Manager.....	J.C. MENARDIE
Sales Manager.....	F. ORY
Quality Management.....	F. ORY
Press Operator	J.C.MENARDIE
Outside Quality	J. BOURDIER
Finance & Administration Manager	J.C. HUVET
Accounting & Administrative Assistant	G. KAPUSTA