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QUALITY MANAGEMENT

"Analysis of UNI EN ISO 9000 Vision 2000. Quality System Documentation"
Lecture - 10 April 2001

LIUC - Castellanza **February - May 2001**

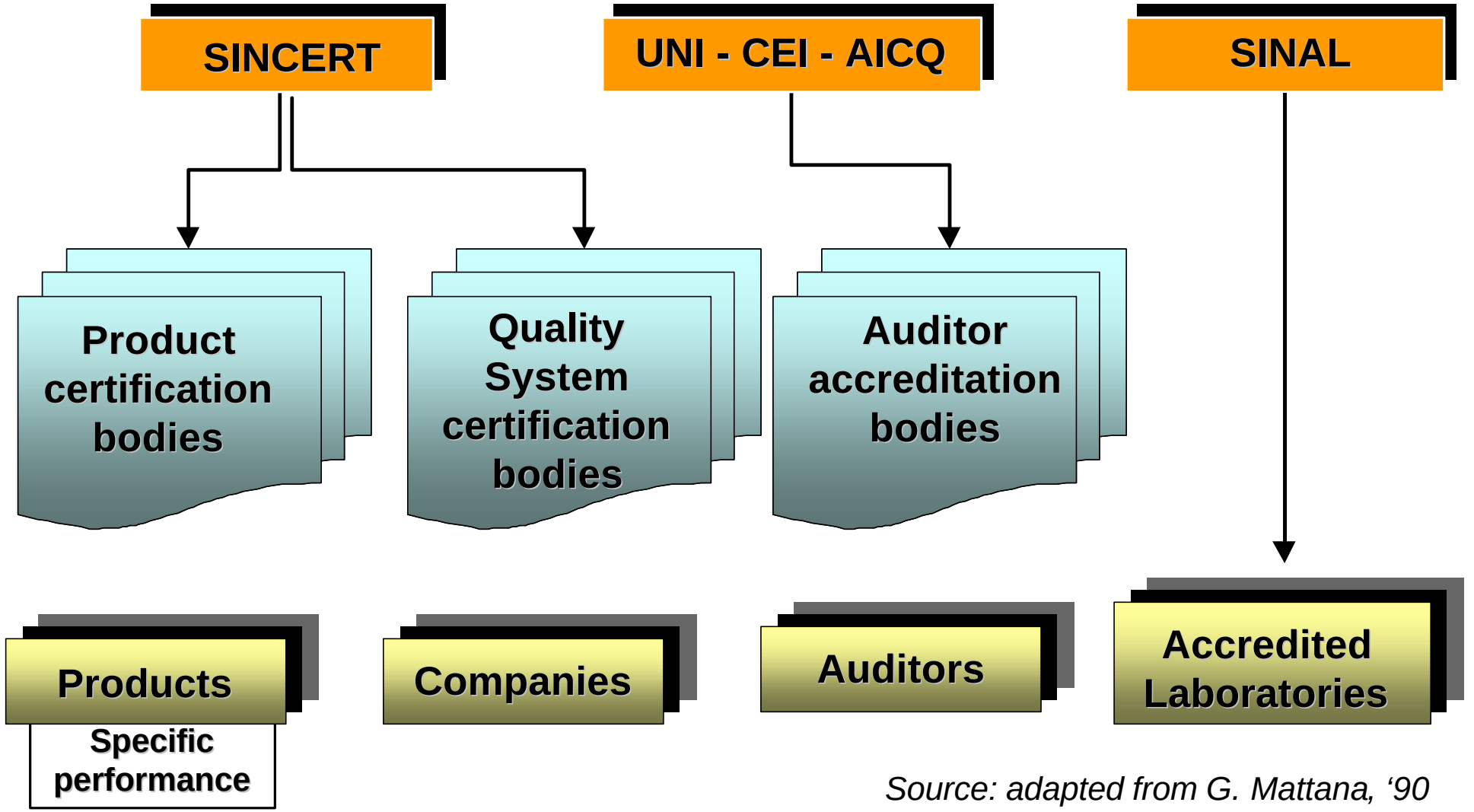
CERTIFICATION: MOTIVATIONS, THE STANDARD AND INTRODUCTION TO VISION 2000

CONTENTS

- HISTORICAL EVOLUTION AND BUSINESS SIGNIFICANCE OF THE QUALITY CONCEPT
- QUALITY PRINCIPLES IN SMEs: PREVENTION, THE CUSTOMER, PROCESSES AND RESOURCES
- THE UPTAKE OF QUALITY SYSTEM CERTIFICATION: SCENARIO DATA
- MOTIVATIONS FOR CERTIFICATION
- THE ISO EN UNI STANDARD FOR QUALITY MANAGEMENT AND QUALITY ASSURANCE
- INTRODUCTION TO VISION 2000

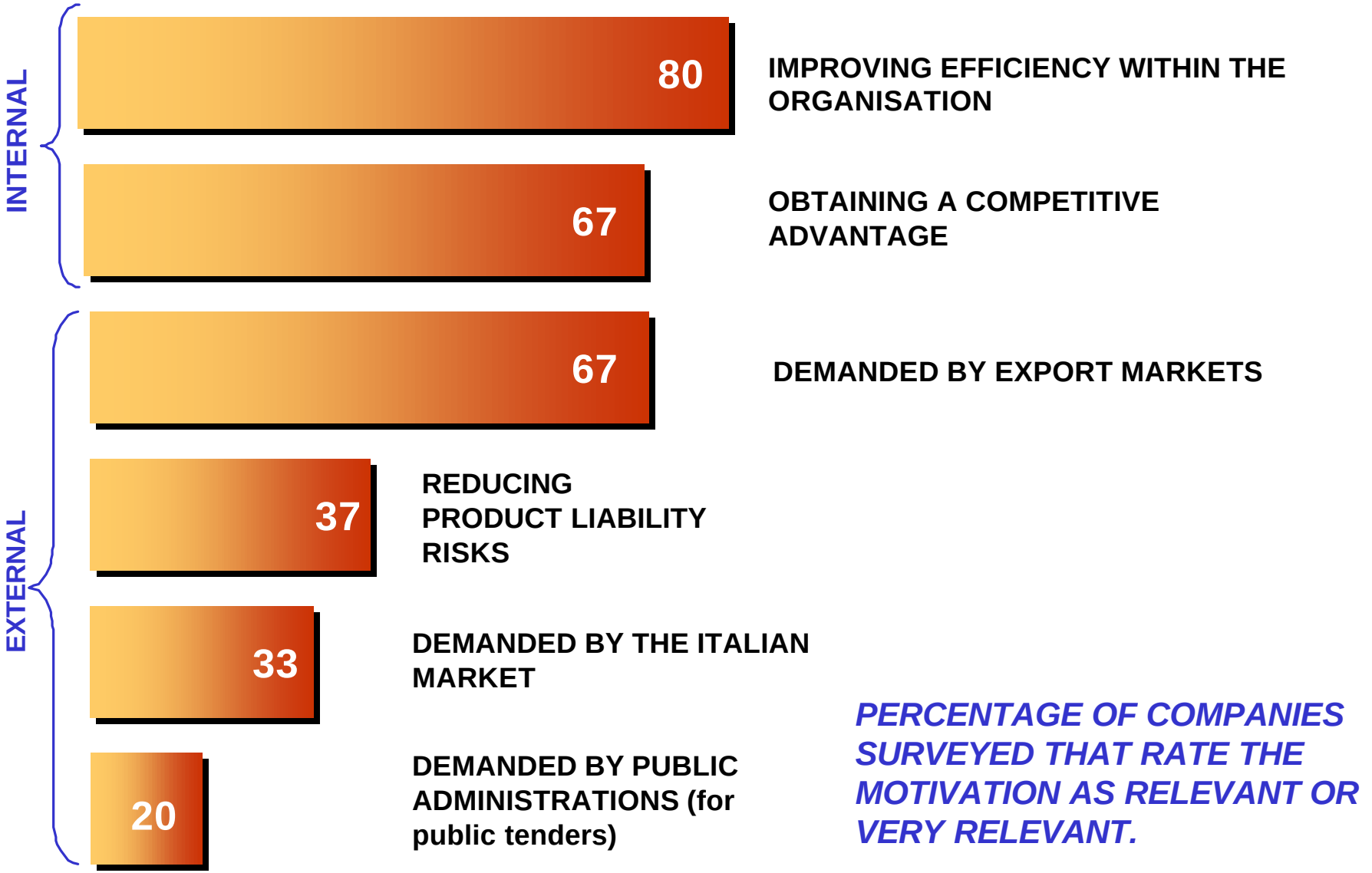
THE INSTITUTIONAL ACTORS IN CERTIFICATION

Three level hierarchy of the different areas of compliance certification



Source: adapted from G. Mattana, '90

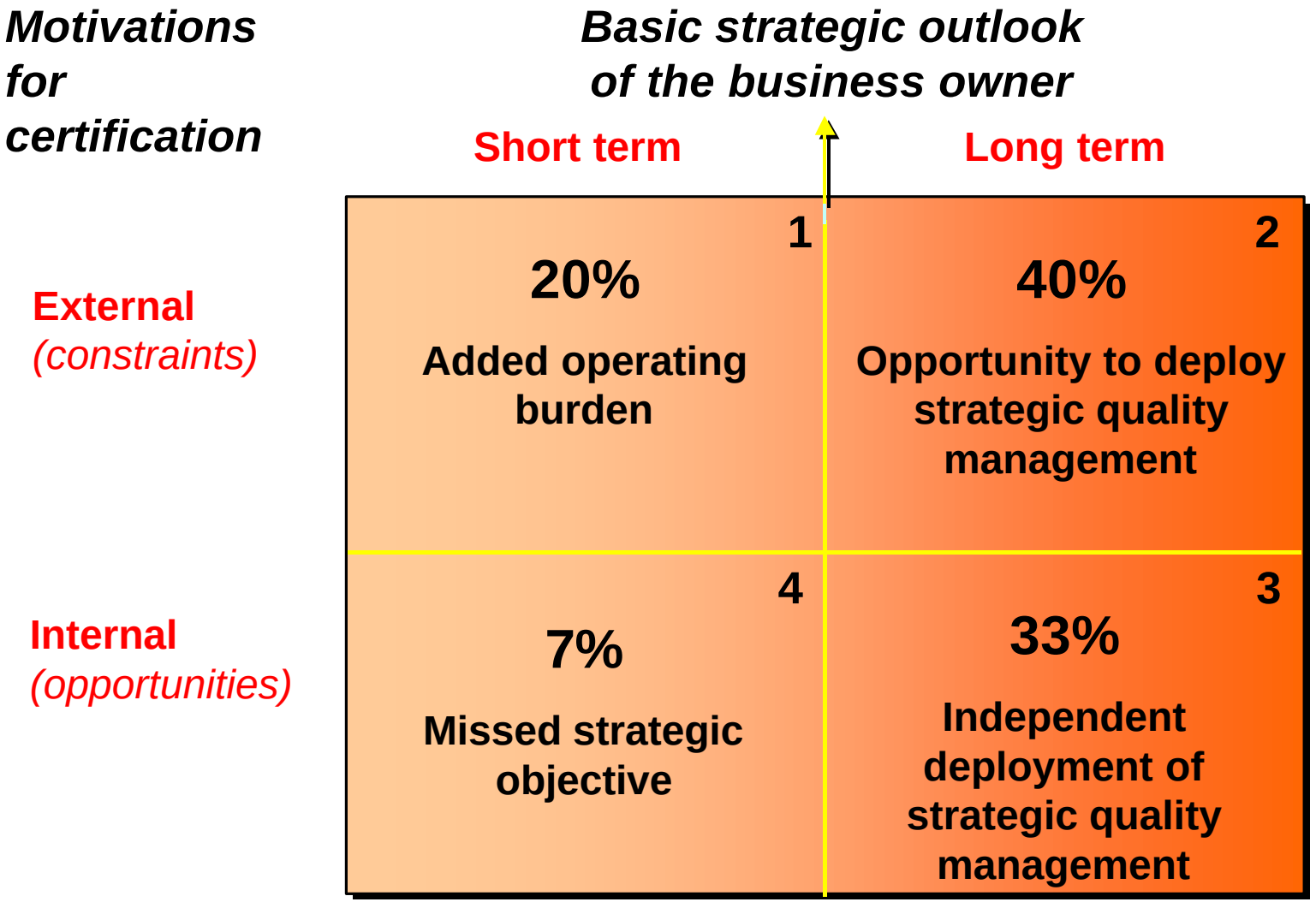
MOTIVATIONS FOR CERTIFICATION



PERCENTAGE OF COMPANIES SURVEYED THAT RATE THE MOTIVATION AS RELEVANT OR VERY RELEVANT.

Source: SDA Bocconi Survey for Assolombarda "Quality for the Development of Small Businesses", October '96.

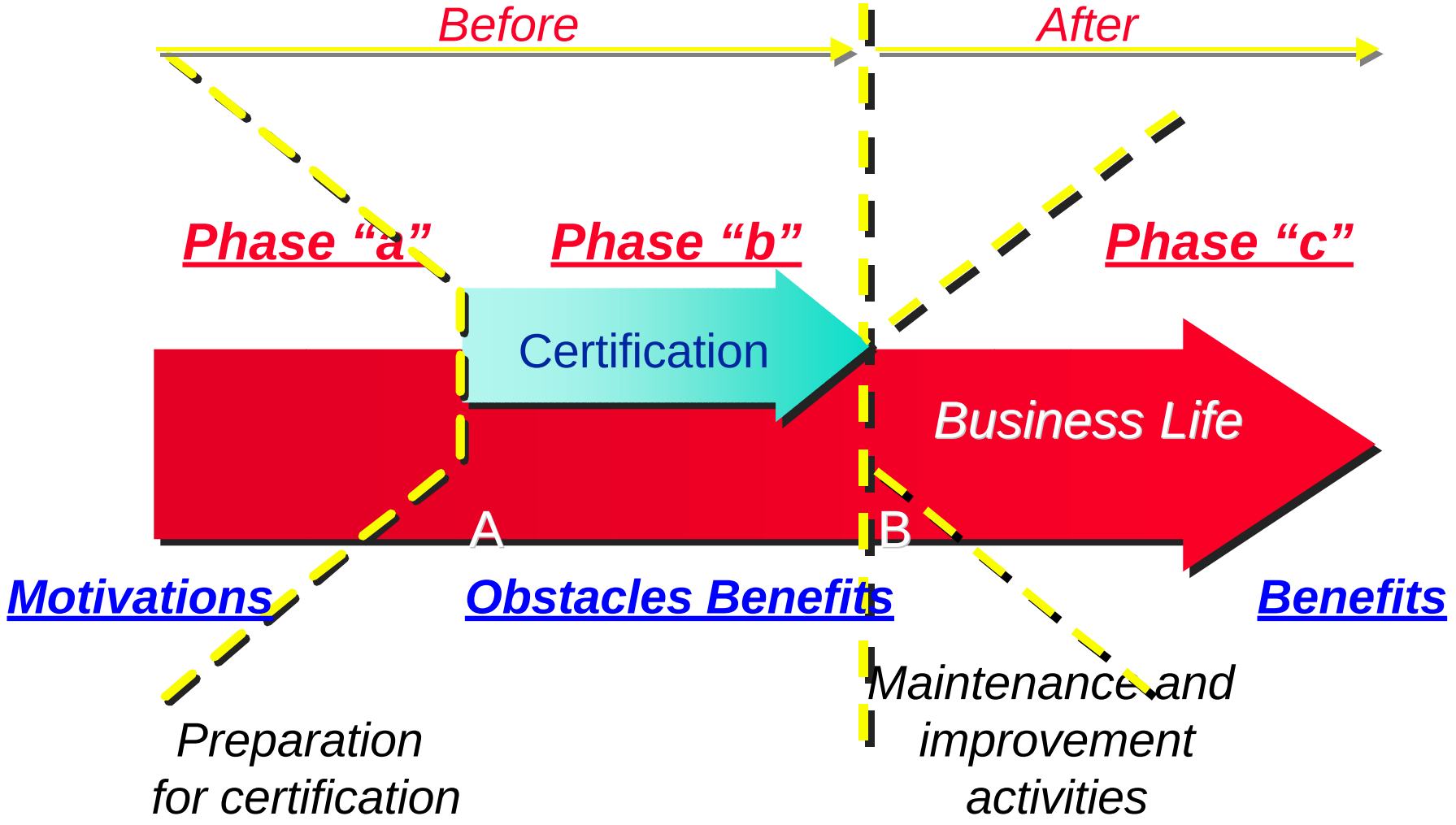
MATRIX FOR THE STRATEGIC ASSESSMENT OF CERTIFICATION



Source: M.G. Conca in *Small and Medium-Sized Enterprises and Facilitating Policies* AA.VV., Egea 1997

THE CERTIFICATION PROCESS

PHASES OF THE CERTIFICATION PROCESS



Source: © Maria Gisella Conca, "Quality for the Development of Small Businesses", 1996.

COMPANY QUALITY SYSTEM CERTIFICATION PROCEDURE

ISO STANDARD CORRESPONDENCE TABLE

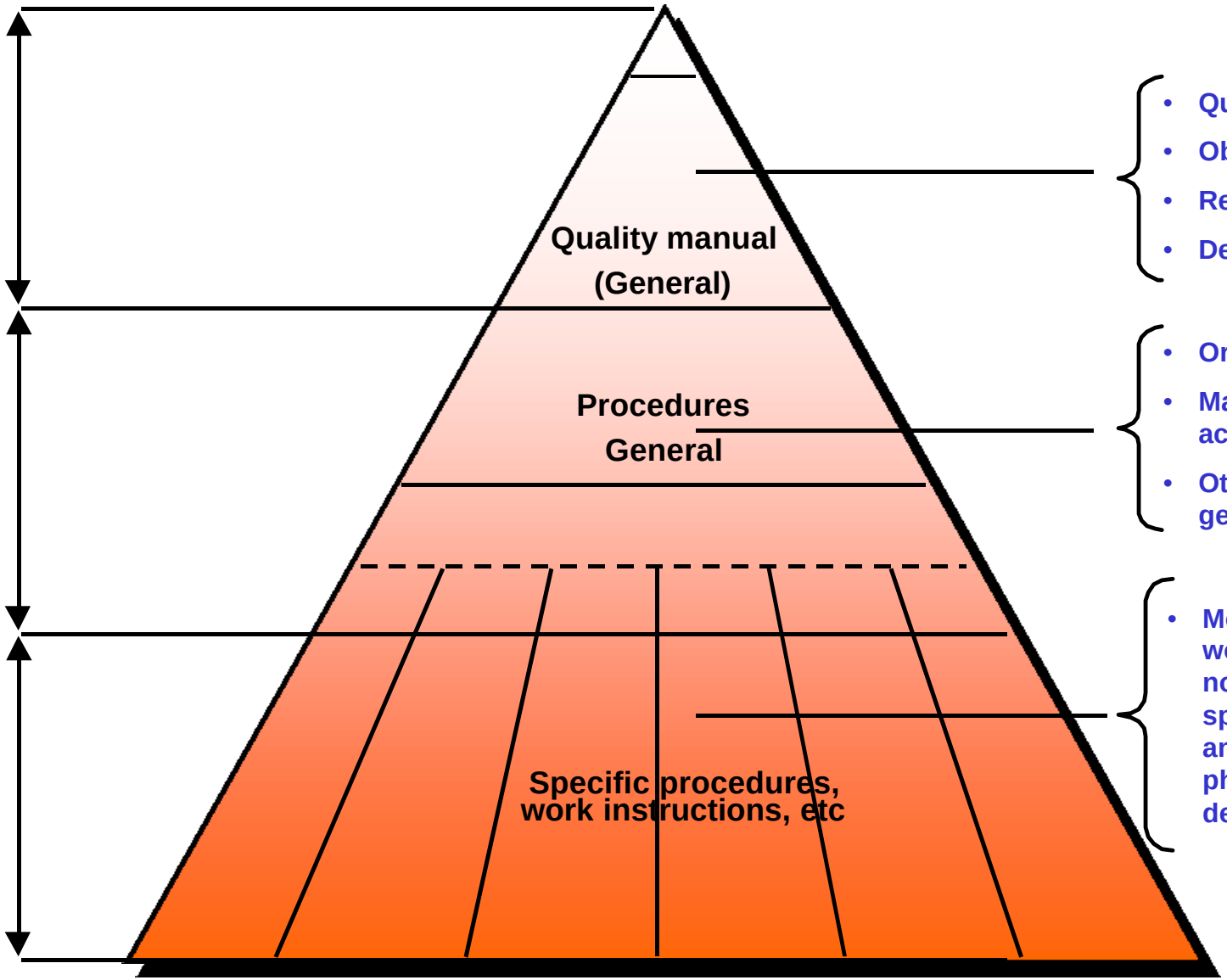
PARAGRAPH OF ISO STANDARD	ISO 9001	ISO 9002	ISO 9003
MANAGEMENT RESPONSIBILITY	4.1 *	*	O
QUALITY SYSTEM	4.2 *	*	O
CONTRACT REVIEW	4.3 *	*	*
PRODUCT DEVELOPMENT AND DESIGN	4.4 *	X	X
DOCUMENT AND DATA CONTROL	4.5 *	*	*
PURCHASING REQUIREMENTS	4.6*	*	X
CUSTOMER-SUPPLIED PRODUCTS	4.7 *	*	*
PRODUCT IDENTIFICATION AND TRACING	4.8 *	*	O
PROCESS CONTROL REQUIREMENTS	4.9 *	*	X
PRODUCT INSPECTION AND TESTING	4.10 *	*	O
CONTROL OF INSPECTION, TEST AND MEASURING EQUIPMENT	4.11 *	*	*
INSPECTION AND TEST STATUS OF PRODUCTS	4.12 *	*	*
CONTROL OF NONCONFORMING PRODUCTS	4.13 *	*	O
CORRECTIVE AND PREVENTIVE ACTION	4.14 *	*	O
HANDLING, STORAGE, PACKAGING PRESERVATION AND DELIVERY	4.15 *	*	*
CONTROL OF QUALITY RECORDS	4.16 *	*	O
INTERNAL QUALITY AUDIT REQUIREMENTS	4.17 *	*	O
TRAINING REQUIREMENTS	4.18 *	*	O
SERVICING REQUIREMENTS	4.19 *	*	X
STATISTICAL TECHNIQUES	4.20 *	*	O

*= Complete requirement

O= More lenient requirement compared with ISO 9001 and 9002

X= Requirement absent

QUALITY SYSTEM DOCUMENTATION

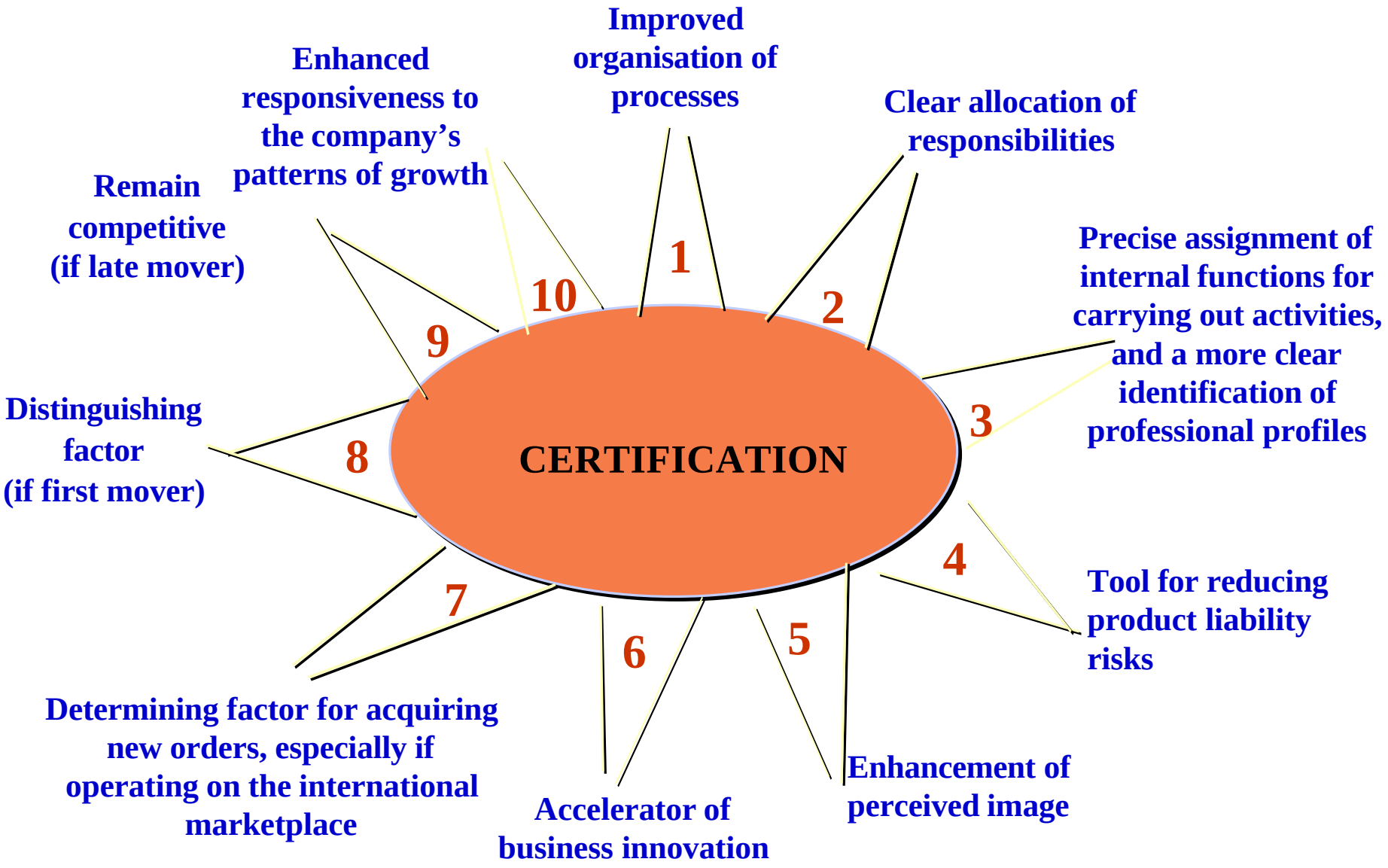


- Quality policy
- Objectives
- Requirements for the QS
- Description of the QS

- Organisation
- Management and control activities
- Other QM activities of a general character

- More detailed procedures, work instructions, etc. normally drawn up for a specific project or product and often divided by topic or phase such as organisation, design, etc

CERTIFICATION AS AN OPPORTUNITY



Quality Manual 3.12

Document which states the quality policy of an organisation and describes its quality system.

Note (1): the quality manual can cover all the activities of an organisation, or only a part of them. The title and purpose of the manual will indicate its scope;

Source: UNI EN ISO 8402 October '95 Quality Management and Quality Assurance; Terms and Definitions

Quality Manual 3.12 (continued)

Note (2): ***the quality manual must, at a minimum, discuss the following: quality policy, responsibilities, organisational structure and patterns of interaction between the people who govern and control activities that affect quality; quality system procedures and instructions; methods for controlling the distribution, review and updating of the manual;***

Note (3): the structure and level of detail of the quality manual can vary depending on the needs of the organisation. It may consist of more than one document. Depending on its scope, the title of the manual may include a qualifier such as: “quality assurance manual” or “quality management manual”.

Source: UNI EN ISO 8402 October ‘95 Quality Management and Quality Assurance; Terms and Definitions

QM –CONTENTS

QUALITY POLICY 3.1

Formal statement by senior management of the organisation's commitment to quality.

Note: the quality policy is an element of corporate policy and must therefore be defined by senior management

Source: UNI EN ISO 8402 October '95 Quality Management and Quality Assurance; Terms and Definitions

QUALITY PLAN 3.13

Document which sets out the specific operating methods, resources and frequency for activities affecting the quality of a given product, project or contract.

Note (1): a quality plan will typically cross-reference the parts of the quality manual that are applicable to a specific case;

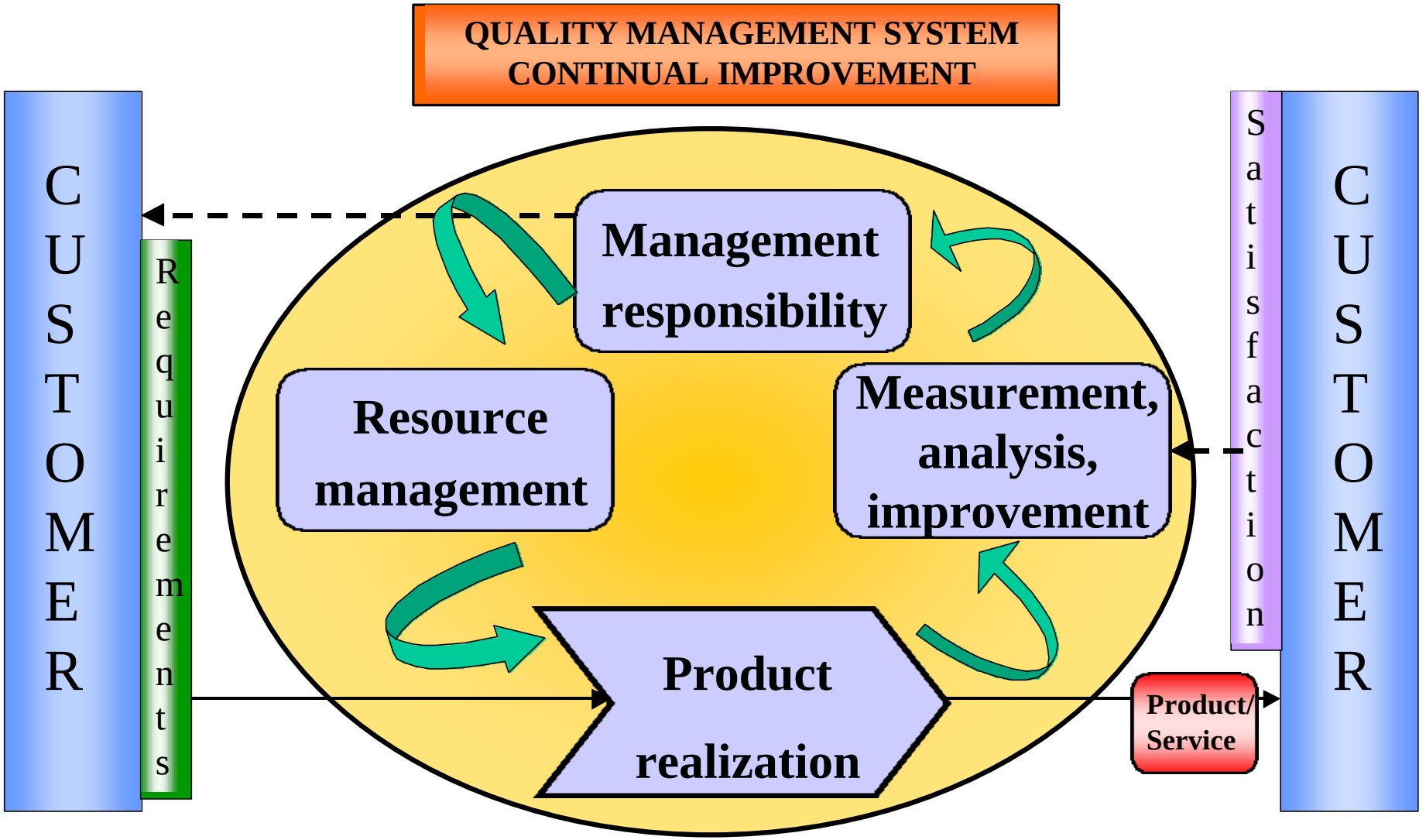
Note (2): depending on its scope, a qualifier may be added to the title: quality assurance plan or quality management plan.

Source: UNI EN ISO 8402 October '95 Quality Management and Quality Assurance; Terms and Definitions

THE ISO 9001: 2000 DOCUMENT issued on 15 December 2000

- **SETS OUT REQUIREMENTS FOR THE "QUALITY MANAGEMENT SYSTEM", RATHER THAN FOR THE "QUALITY SYSTEM" AS PREVIOUSLY**
- **EXPLICITLY ENCOURAGES ADOPTION OF A PROCESS APPROACH**
- **IS COMPATIBLE WITH OTHER MANAGEMENT SYSTEMS, FOR EXAMPLE WITH THE ISO 14001 ENVIRONMENTAL MANAGEMENT SYSTEM**

QUALITY MANAGEMENT PROCESS MODEL



THE SCOPE OF THE STANDARD HAS CHANGED OVER TIME

- **IN ’87 THE FOCUS WAS ON THE PREVENTION OF NONCONFORMITIES**
- **IN ’94 THE FOCUS WAS ON THE CUSTOMER, BUT NOT ON EFFECTIVENESS OR CONTINUAL IMPROVEMENT**
- **IN 2000 THE ORIENTATION OF THE STANDARD IS TOWARD THE MANAGEMENT SYSTEM OF THE ORGANISATION**

SOME REASONS FOR THE REVISION OF THE STANDARD

- **REVISION SCHEDULED EVERY 5 YEARS**
- **DIFFICULTIES ASSOCIATED WITH THE STRUCTURE OF 20 ELEMENTS, REQUIREMENTS**
- **DIFFICULTY IN APPLYING THE STANDARD TO SMALL BUSINESSES**
- **EXCESSIVELY PRODUCTION ORIENTED**
- **PROLIFERATION OF ISO 9000 FAMILY DOCUMENTS**
- **NEED TO MOVE BEYOND CERTIFICATION, TOWARD CONTINUAL IMPROVEMENT**