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QUALITY MANAGEMENT

***“The process of obtaining certification.
Exemple of Procedure”***

LIUC - Castellanza

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THE PROCESS OF OBTAINING CERTIFICATION

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REGISTRATION AGENCY**

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➤ **EXEMPLE OF PROCEDURE**

➤ **CERTIFICATION AS AN OPPORTUNITY?**

➤ **THE PRINCIPAL OBSTACLES AND BENEFITS FOR SMEs:
RESULTS OF A FIELD SURVEY AND THE RESPONSES **OF**
BUSINESS OWNERS**

PHASES OF CERTIFICATION UNDER UNI EN ISO 9001

1. PREPARATION

- Submission of Certification Application and Quality Manual(*)
- Evaluation of documentation
- Acceptance of application
- Optional pre-assessment

2. CERTIFICATION

- Planning the quality audit
- Performing the quality audit
- Audit report
- Implementation of any corrective actions by the company
- Review by Certification Committee
- Ratification by Executive Committee
- Issuing of Certification

3. MAINTENANCE AND RENEWAL

- Annual surveillance audits, with a more in-depth renewal audit carried out on the 3rd year after certification.

Source: <http://www.certiquality.it/HTML/ISO9000.HTM> (Certiquality)

ISO 9001:1994 QUALITY ASSURANCE MODEL REQUIREMENTS

ISO 9001:1994

ADMINISTRATION & CONTROL

- 4.1 Management Responsibility**
- 4.2 Quality System**
- 4.5 Document and Data Control**
- 4.8 Product Identification & Traceability**
- 4.11 Control of Inspection, Measurement, and Test Equipment**
- 4.12 Inspection and Test Status**
- 4.13 Control of Nonconforming Product**
- 4.16 Control of Quality Records**

ISO 9001:1994 QUALITY ASSURANCE MODEL REQUIREMENTS

ISO 9001:1994

PRODUCT REALIZATION

4.3 Contract Review

4.4 Design Control

4.6 Purchasing

4.7 Control of Customer-Supplied Product

4.9 Process Control

4.10 Inspection and Testing

4.15 Handling, Storage, Packaging, Preservation, and Delivery

4.19 Servicing

ISO 9001:1994 QUALITY ASSURANCE MODEL REQUIREMENTS

ISO 9001:1994

SUPPORT ACTIVITIES

4.14 Corrective and Preventive Action

4.17 Internal Quality Audits

4.18 Training

4.20 Statistical Techniques

ISO 9001:2000 PROCESS MODEL FOR QUALITY MANAGEMENT

QUALITY MANAGEMENT SYSTEM

ISO 9001:2000

4.1, 4.2 General, Documentation Requirements

MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning

5.5 Responsibility, Authority and Communication

5.6 Management Review

ISO 9001:2000 PROCESS MODEL FOR QUALITY MANAGEMENT

RESOURCE MANAGEMENT

ISO 9001:2000

6.1 Provision of Resources

6.2 Human Resources

6.3 Infrastructure

6.4 Work Environment

PRODUCT REALIZATION

7.1 Planning of Product Realization

5.2 Customer-Related Processes

7.3 Design and Development

7.4 Purchasing

7.5 Production and Service Provision

7.6 Control of Monitoring and Measuring Devices

ISO 9001:2000 PROCESS MODEL FOR QUALITY MANAGEMENT

MEASUREMENT, ANALYSIS AND IMPROVEMENT

ISO 9001:2000

- 8.1** **General**
- 8.2** **Monitoring and Measurement**
- 8.3** **Control of Nonconforming Product**
- 8.4** **Analysis of Data**
- 8.5** **Improvement**

DIFFERENCES BETWEEN DOCUMENTS AND RECORDS

ISO 9001 establishes different requirements for DOCUMENTS and RECORDS

DOCUMENTS in ISO 9001 consist of permanent documentation. They describe and define important part of Organization like systems, processes, procedures, and products.

RECORDS report elements or results achieved in historic evidence of activities conducted like test records, evidence of verification, preventive and corrective action

QUALITY PROCEDURES

THERE ARE 7 IMPORTANT POINT FOR A QUALITY PROCEDURE:

- **PURPOSE/OBJECTIVE**
- **SCOPE**
- **RESPONSIBILITIES**
- **REFERENCES**
- **DEFINITIONS**
- **PROCEDURES**
- **DOCUMENTATION**

PROCEDURE EXEMPLE

DOCUMENT CONTROL PROCEDURE (1/3)

PURPOSE

This document describes the procedure to be followed for the approval, issue, and maintenance of all controlled documentation.

SCOPE

This procedure shall apply to all controlled documentation relating to all Company products and services.

REFERENCES

Document Change Procedure DOC – PROC – 001

Document Register DOC – REG – 001

Source: "ISO 9000 Handbook", Irwin Professional Publishing, 1994

PROCEDURE EXEMPLE

DOCUMENT CONTROL PROCEDURE (2/3)

PROCEDURE

All controlled documentation shall be subject to approval by the following before issue and release:

- **Originator**
- **Originator's manager**
- **Quality manager**

Released documentation can only be changed in accordance with the Change Control System DOC – PROC – 001.

A record of all controlled documentation shall be maintained by the quality manager indicating the following:

- **Reference number**
- **Issue number**
- **Disposition of copies**

Source: "ISO 9000 Handbook", Irwin Professional Publishing, 1994

PROCEDURE EXEMPLE

DOCUMENT CONTROL PROCEDURE (3/3)

Details of controlled document holders shall be held on the Document Register

Officially distributed copies of the documents shall be identified by a red “Official Distribution” stamp giving date of distribution. Action affecting Product quality shall only be taken on the basis of information contained in Officially distributed copies of controlled documents.

Master copies of all controlled documentation shall be held by the quality manager.

All copies of documentation that become obsolete by reissue shall be Promptly removed from distribution. One copy shall be archived by the quality Manager;all other copies shall be destroyed.

Source: “ISO 9000 Handbook”, Irwin Professional Publishing, 1994

CERTIFICATION AS AN OPPORTUNITY

THE FLIP SIDE OF THE COIN

**1-IMPROVED
ORGANISATION
OF PROCESSES**

↪ **NOTHING CHANGES, I AM
ONLY DESCRIBING WHAT
IS ALREADY BEING DONE**

**2- CLEAR ASSIGNMENT
OF RESPONSIBILITIES**

↪ **PEOPLE FEEL
OVERWHELMED,
AT TIMES LEFT OUT
OR ENGULFED BY
UNDESIRED PAPERWORK
OR RIGID PROCEDURES
(FORM OVER
FUNCTION)**

CERTIFICATION AS AN OPPORTUNITY

THE FLIP SIDE OF THE COIN

**3- SPECIFIC ASSIGNMENT
OF ROLES AND CLEARER
IDENTIFICATION
OF PROFESSIONAL
PROFILES**

↪ **I DON'T HAVE THE RESOURCES
TO ACQUIRE THE NECESSARY
SKILLS**

**4- A TOOL FOR REDUCING
PRODUCT LIABILITY
RISKS**

↪ **NOT RELEVANT IN OUR CASE**

**5- ENHANCEMENT OF
PERCEIVED IMAGE**

↪ **I DON'T HAVE THE
CONTRACTUAL POWER TO
PAY BACK THE INVESTMENT**

CERTIFICATION AS AN OPPORTUNITY

THE FLIP SIDE OF THE COIN

**6-ACCELERATOR OF
INNOVATION**

↪ **TOO MANY INVESTMENTS,
I AM UNABLE TO SUSTAIN
THE BURDEN**

**7-NEW ORDERS FROM
EXPORT MARKETS**

↪ **THIS ASPECT IS NOT
RELEVANT TO US**

**8-FIRST MOVER
ADVANTAGE**

↪ **NOT WORTHWHILE, THE
COMPETITIVE ADVANTAGES
IN OUR SECTOR ARE
DIFFERENT**

CERTIFICATION AS AN OPPORTUNITY

THE FLIP SIDE OF THE COIN

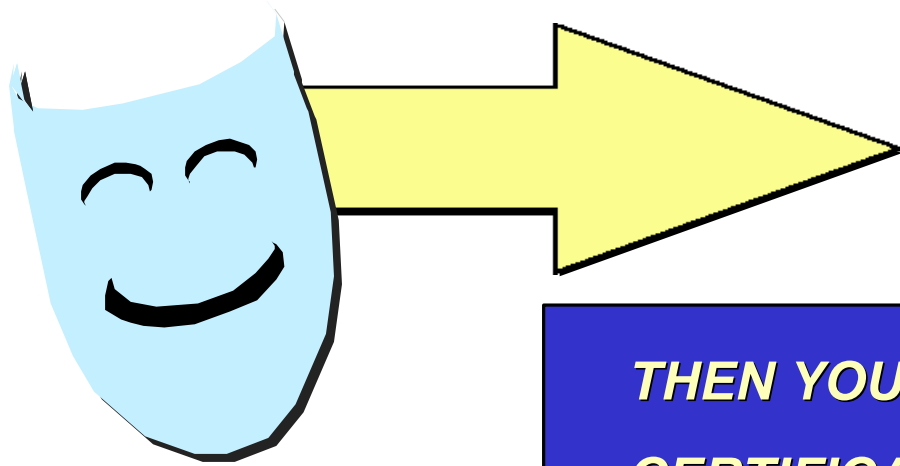
9- FORCED COMPLIANCE

↪ **IF WE REALLY HAVE TO
DO IT**

**10- ENHANCED
RESPONSIVENESS TO THE
COMPANY'S PATTERNS OF
GROWTH**

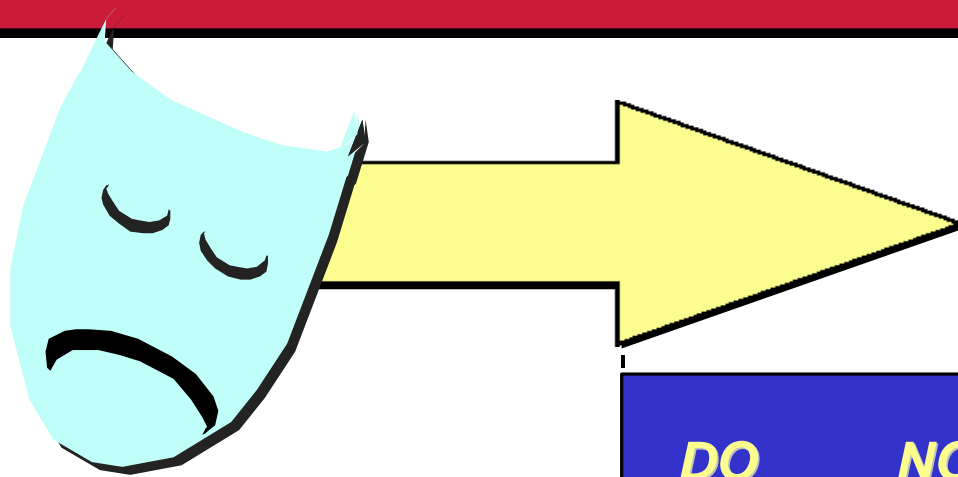
↪ **THE QUALITY MANUAL
AND THE PROCEDURES
IMPAIR THE COMPANY'S
FLEXIBILITY**

**IF YOU HAVE FOUND AT LEAST TWO VALID
MOTIVATIONS FOR CERTIFICATION WITHIN YOUR
COMPANY, OR IF ONE OF THEM IS ABSOLUTELY
ESSENTIAL FOR BUSINESS SURVIVAL**



***THEN YOU SHOULD CONSIDER
CERTIFICATION AS A STRATEGIC
ELEMENT FOR YOUR COMPANY
AND ACT ACCORDINGLY.***

**IF YOU FOUND THAT ALL THE ANSWERS IN THE
RIGHT HAND COLUMN WERE APPLICABLE TO
YOUR COMPANY**



***DO NOT UNDERTAKE THE
CERTIFICATION PROCESS: IT WOULD
BE A LENGTHY, PAINFUL,
UNREWARDING AND EXPENSIVE
EXPERIENCE.***

Study for the Assolombarda Quality Consortium

***QUALITY FOR THE
DEVELOPMENT OF SMALL
BUSINESSES***

by

MARIA GISELLA CONCA

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- 1- OBJECTIVES AND METHODS OF THE STUDY**
- 2- THE SAMPLE OF COMPANIES**
- 3- THE MOTIVATIONS FOR CERTIFICATION**
- 4- OBSTACLES AND **BENEFITS** IN THE CERTIFICATION PROCESS**
- 5- RESULTS **DERIVED FROM THE** IMPLEMENTATION OF THE QUALITY SYSTEM**
- 6- CONSIDERATIONS AND COMMENTS OF THE RESPONDENTS**
- 7- COMPANIES AND THE EVOLUTIONARY **MODEL** FOR STRATEGIC QUALITY MANAGEMENT**

OBJECTIVES OF THE STUDY

TO DETERMINE WHETHER, AND UNDER WHICH CONDITIONS, **THE CERTIFICATION PROCESS IS EFFECTIVE IN STIMULATING THE DEVELOPMENT AND IMPROVEMENT OF SMEs**

1- TO INVESTIGATE:

- - MOTIVATIONS - OBSTACLES – BENEFITS - COSTS**
- RESULTS**

OBJECTIVES OF THE STUDY (continued)

2- TO MEASURE:

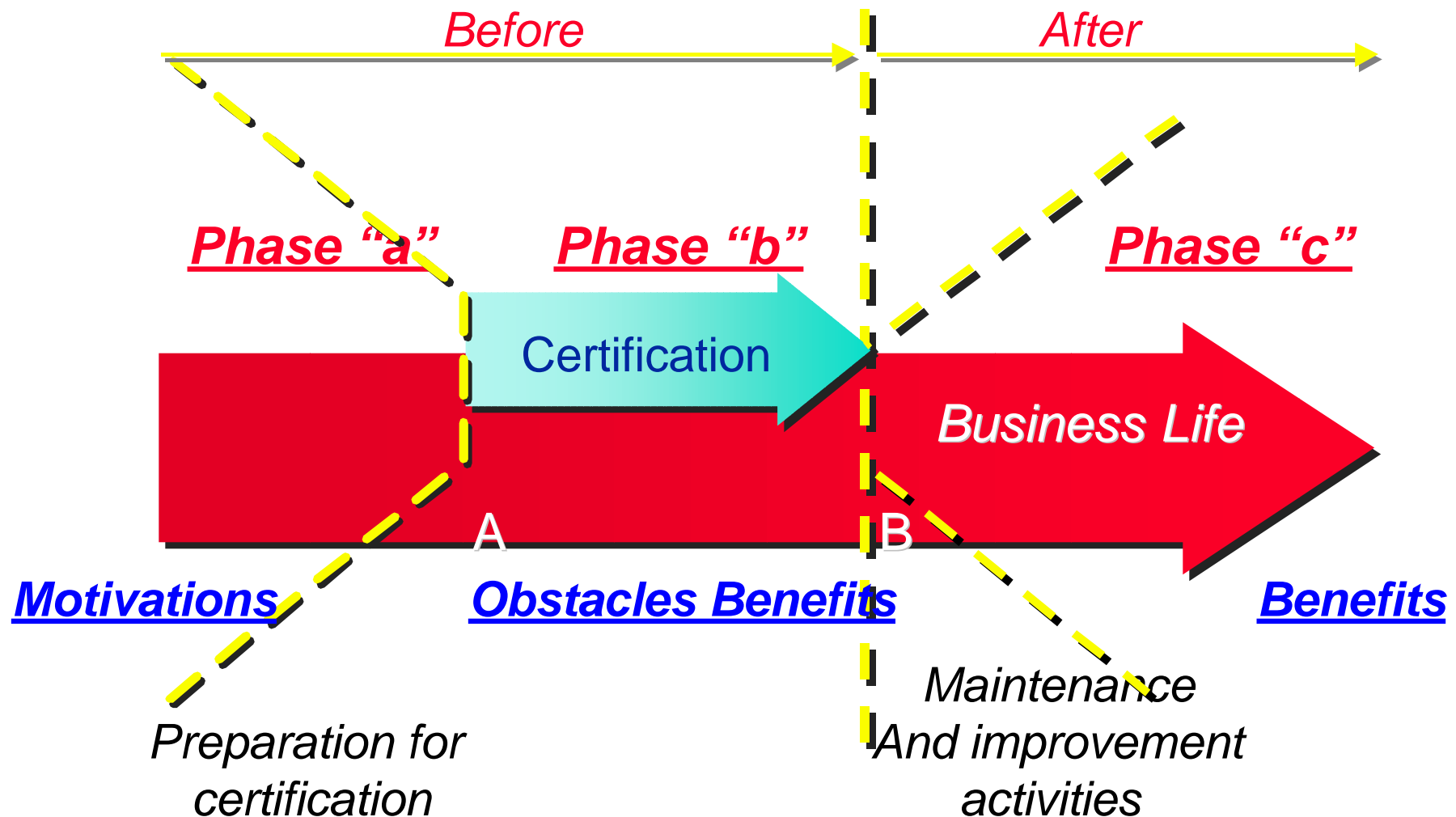
- **THE SATISFACTION OF BUSINESS OWNERS WITH THE SERVICES OFFERED BY THE INSTITUTIONAL ACTORS**

3- TO DETERMINE:

- **THE POSITIONING OF BUSINESSES ON THE EVOLUTIONARY PATHWAY TOWARD TOTAL OR STRATEGIC QUALITY MANAGEMENT**

THE CERTIFICATION PROCESS

PHASES OF THE CERTIFICATION PROCESS



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

METHODOLOGY OF THE STUDY

- **ANALYSIS OF INDIVIDUAL COMPANY CASE STUDIES WITHIN THE CONTEXT OF THE CERTIFICATION PROCESS AS A WHOLE**
- **QUESTIONNAIRE DEVELOPED AD HOC FOR COLLECTING INFORMATION OF A GENERAL CHARACTER, INFORMATION ABOUT THE CERTIFICATION PROCESS, RESULTS AND COMMENTS**
- **INTERVIEWS IN THE FIELD DIRECTED CHIEFLY AT BUSINESS OWNERS OR QUALITY MANAGERS**

THE SAMPLE OF COMPANIES

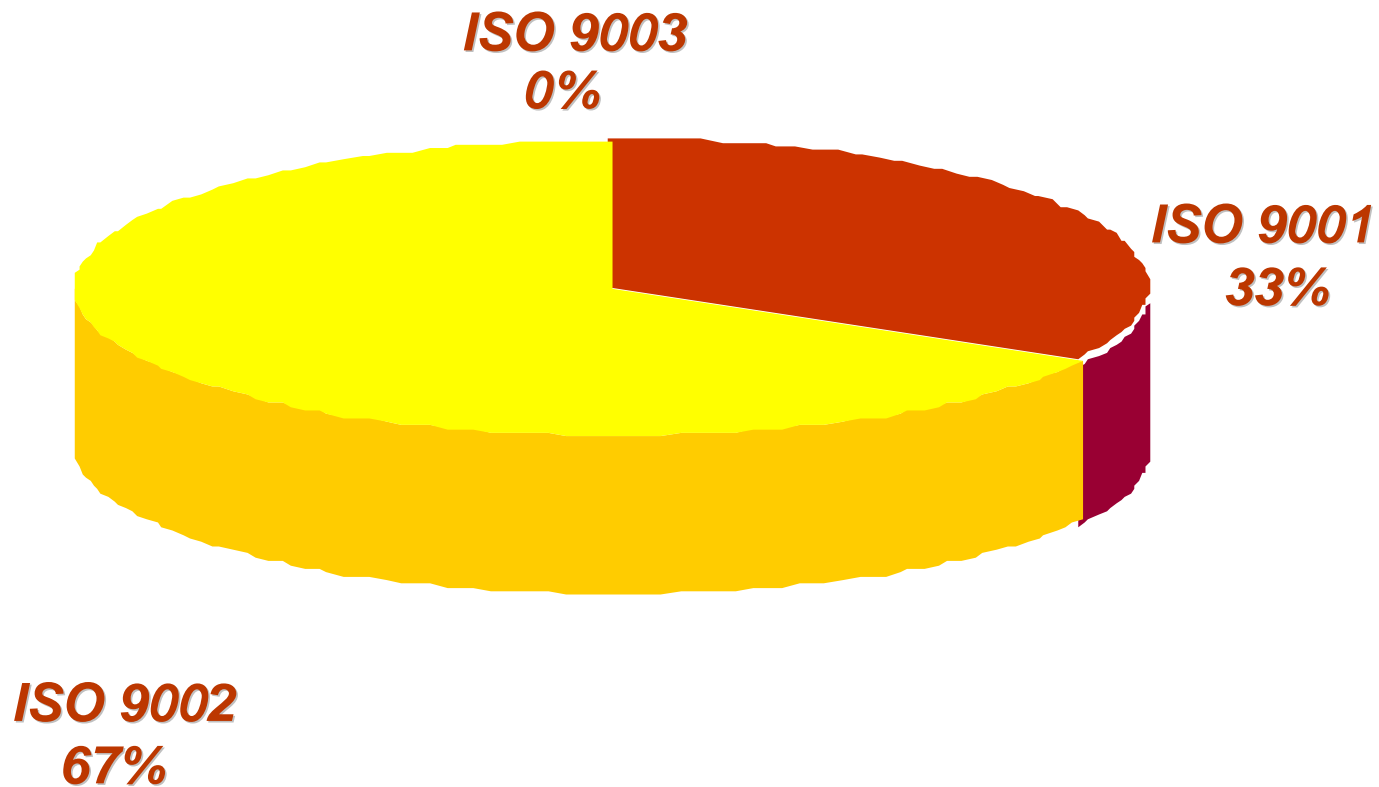
'95 turnover bn lire	%Var. in turnover from '93 to '95	% Export turnover	Number of employees	Turnover bn/employees	Registration Agency
6.5	+ 33	20	23	282	ICIM
7.0	+133	17	20	350	ICIM
7.0	+ 17	2	50	140	DNV
7.3	+ 46	30	32	228	ICIM
8.5	- 30	20	29	293	CSQ
10.0	+ 33	65	40	250	CSQ
11.0	+ 70	25	35	314	CSQ
11.2	+ 49	42	80	140	IGQ
11.5	+ 15	15	41	280	ICIM
12.0	+ 33	80	65	185	ICIM
13.5	+ 59	46	28	483	CSQ
14.0	+ 40	-	21	666	BUR VERI
14.5	+ 12	38	72	201	DNV
14.8	+ 35	35	15	987	CSQ
17.0	+ 42	20	89	191	CSQ

THE SAMPLE OF COMPANIES (continued)

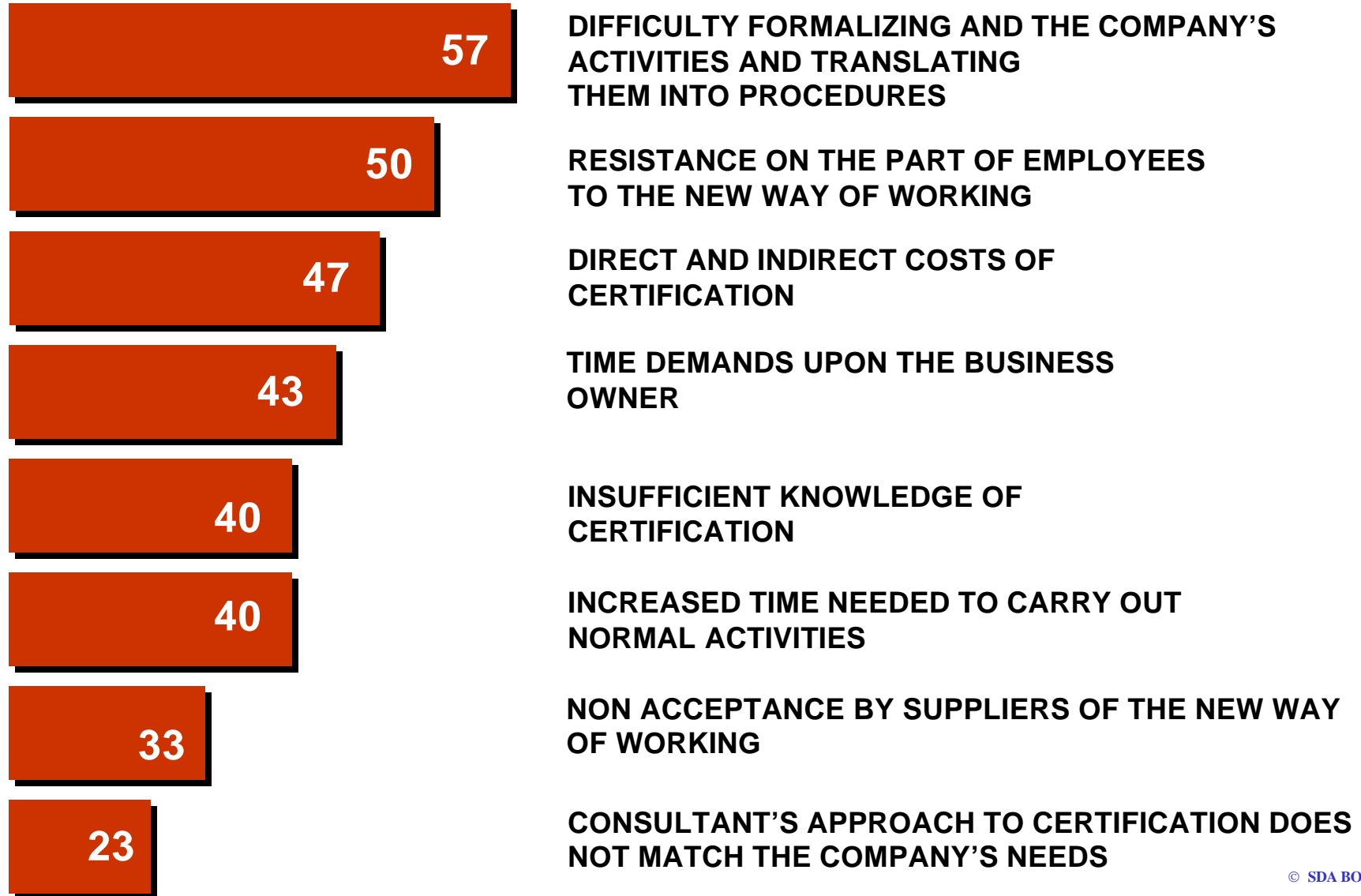
'95 turnover bn lire	% Var. in turnover from '93 to '95	% Export turnover	Number of employees	Turnover (bn)/employees	Registration agency
18.5	+ 23	60	50	370	SGS
18.5	-	47	87	213	CSQ
18.9	+ 11	60	87	217	ICIM
20.4	+ 46	50	78	262	ICIM
21.5	+ 34	15	40	537	CSQ
23.7	+ 41	40	93	255	RINA
25.0	+127	-	140	179	CSQ
28.0	+ 65	50	95	295	CSQ
28.3	+ 18	35	88	322	IIP
29.0	+ 21	6	35	829	CERTICHIM
33.0	+ 57	45	100	330	IIP
36.5	+ 52	11	65	562	CSQ
39.0	+ 63	18	120	325	CSQ
47.0	+ 68	27	35	1343	CERTICHIM
58.0	+115	91	200	290	ICIM

THE SAMPLE OF COMPANIES (continued)

TYPE OF ISO CERTIFICATION OBTAINED



THE PRINCIPAL OBSTACLES



THE BENEFITS

BENEFITS PERCEIVED BY COMPANIES DURING THE INITIAL PHASES OF THE PROCESS

DETECTING AND GAINING AWARENESS OF INEFFICIENCIES WITHIN THE COMPANY **87**

IMPROVED MANAGEMENT OF COMPANY PROCESSES **83**

GREATER INVOLVEMENT OF MANAGERS **83**

73 INVOLVEMENT OF PEOPLE IN COMPANY PROCESSES

57 IMPROVED MOTIVATION OF PEOPLE

57 INCREASED CUSTOMER CONFIDENCE

20 IMPROVED RELATIONS WITH SUPPLIERS

BENEFITS PERCEIVED BY COMPANIES AFTER OBTAINING CERTIFICATION

IMPROVED IMAGE OF THE COMPANY **90**

IMPROVED RELATIONS WITH CUSTOMERS **67**

53 REDUCTION IN CUSTOMER INSPECTIONS

47 IMPROVED CLIMATE WITHIN THE COMPANY

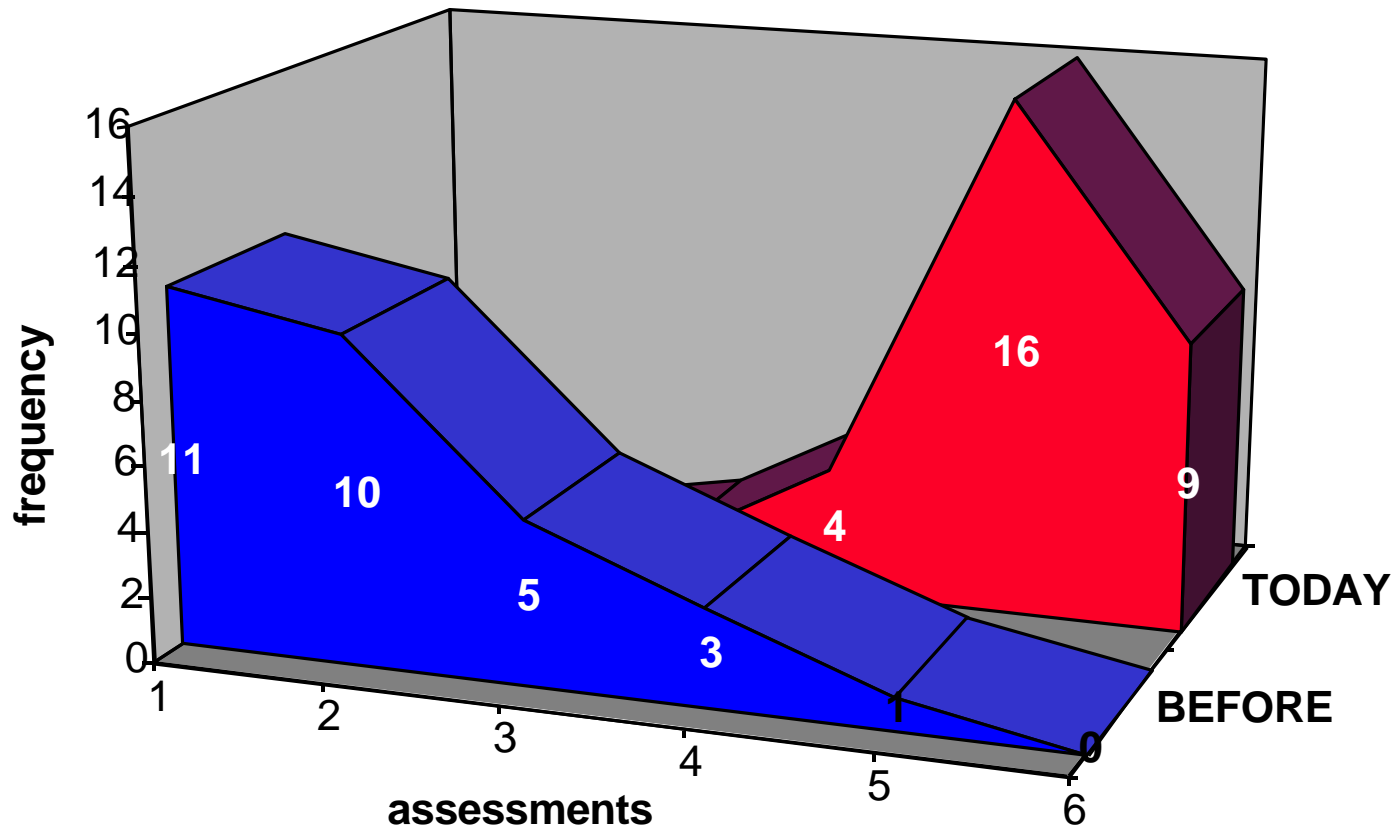
43 REDUCTION IN PROCESS WASTE

37 INCREASED NUMBER OF CUSTOMER

30 REDUCTION IN COSTS

RESULTS DERIVED FROM THE IMPLEMENTATION OF THE QUALITY SYSTEM

a. Formalisation and description of company processes

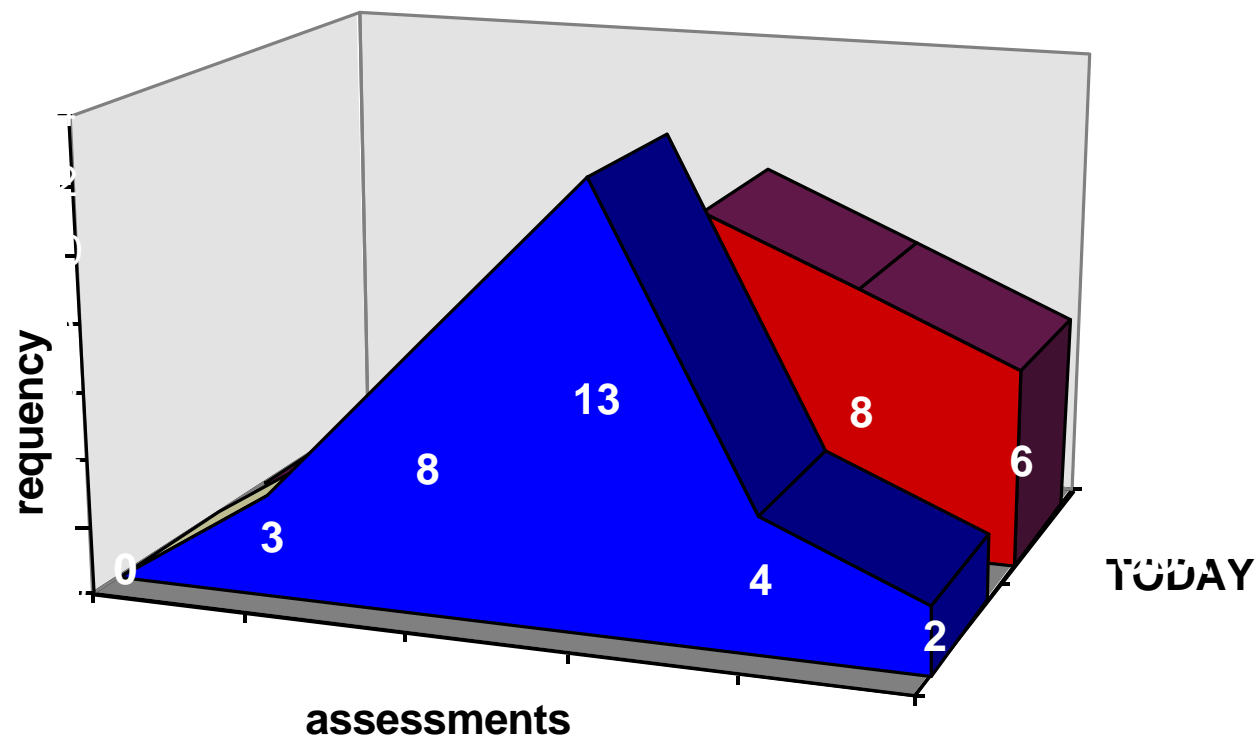


1= not formalised 6= fully formalised

RESULTS DERIVED FROM THE IMPLEMENTATION OF THE QUALITY SYSTEM

(continued)

g. Economic-financial results



1= significant losses

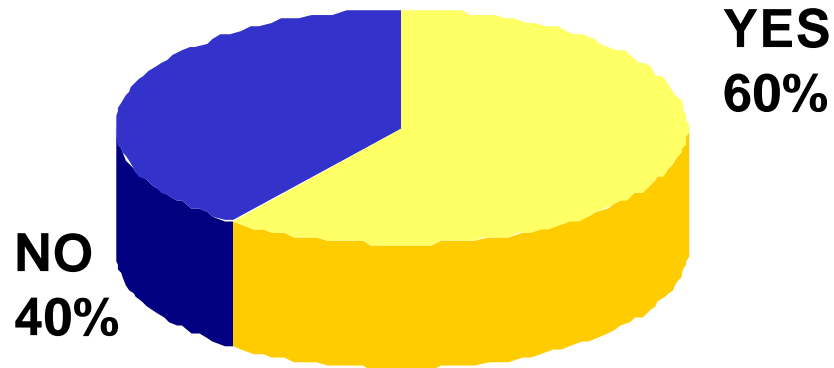
6= substantial profits

RESULTS DERIVED FROM THE IMPLEMENTATION OF THE QUALITY SYSTEM

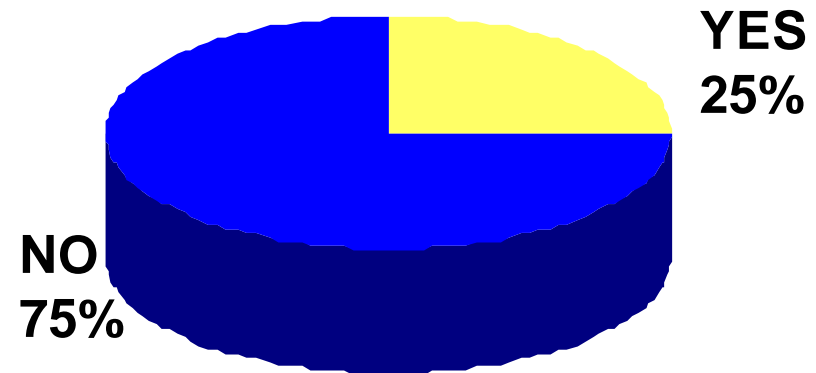
(continued)

GAINING A COMPETITIVE ADVANTAGE FOLLOWING CERTIFICATION OF THE QUALITY SYSTEM

Total Sample



Total companies with turnover <17 bn



CONSIDERATIONS AND COMMENTS OF THE RESPONDENTS

- **ALL RESPONDENTS SAID THEY HAVE PLANNED IMPROVEMENT **ACTIVITIES**. 37% OF THEM SAID THEY ENCOUNTERED DIFFICULTIES IN THE IMPLEMENTATION.**
- **57% OF COMPANIES IN THE SAMPLE HAVE RECEIVED SUBSIDIES **FROM LOMBARDY REGION**. 70% OF THEM DESCRIBED THEMSELVES AS SATISFIED.**

CONSIDERATIONS AND COMMENTS OF THE RESPONDENTS (continued)

- **60% OF RESPONDENTS DESCRIBED THE CONSULTANCY COSTS AS HIGH, WHILE 23% OF COMPANIES SAID THE CONSULTANT'S APPROACH FAILED TO MATCH THEIR NEEDS.**
- **ONLY 1/3 OF THE SAMPLE DESCRIBED THE COSTS OF THE REGISTRATION AGENCY AS CONSIDERABLE. HOWEVER THERE IS A NEED FOR SIMPLIFIED PROCEDURES FOR SMEs. IN SOME CASES THE EXPERIENCE AND PROFESSIONALISM OF THE AUDITORS WAS APPRECIATED.**