METODI STATISTICI-QUALITÀ-AFFIDABILITÀ

IL QUADRO NORMATIVO

aicq
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Centronord

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LA PIÙ RILEVANTE INNOVAZIONE RECENTE DELLA NORMATIVA

Che cos'è un Sistema di Gestione?

Dalla ISO 9001 alle norme di approfondimento

ISO 9001:2015

STANDARD/ DOCUMENT	TITLE	EDITION	PUBLICATION DATE	COMMENT	MSS TYPE
ISO 10001:2007	Quality management – Customer satisfaction – Guidelines on codes of conduct for organizations	First	2007-01-12		B
ISO 10002:2004	Quality management – Customer satisfaction – Guidelines for complaints handling in organizations	First	2004-07-01		B
ISO 10003:2007	Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations	First	2007-01-12		B
ISO/TS 10004:2010	Quality management – Customer satisfaction – Guidelines for monitoring and measuring	First	2010-06-25	Revised by ISO/DIS 10004	B
ISO 10005:2005	Quality management – Guidelines for quality plans	Second	2005-06-01		B
ISO 10006:2003	Quality management – Guidelines for quality management in projects	Second	2003-06-15		B
ISO 10007:2003	Quality management – Guidelines for configuration management	Second	2003-06-15		B
ISO 10012:2003	Measurement management systems – Requirements for measurement processes and measuring equipment	Second	2003-04-14		A
ISO/TR 10013:2001	Guidelines for quality management system documentation	Second	2001-07-15		B
ISO 10014:2006	Quality management – Guidelines for realizing financial and economic benefits	First	2006-07-01		B
ISO 10015:1999	Quality management – Guidelines for training	First	1999-12-15		B
ISO/TR 10017:2003	**Guidance on statistical techniques for ISO 9001:2000**	Second	2003-05-15		B
ISO 10019:2005	Guidelines for the selection of quality management system consultants and use of their services	First	2005-01-05		B
ISO 19011:2011	Guidelines for auditing management systems	Second	2011-11-11		B
ISO/FDIS 10018	Quality management – Guidelines on people involvement and competence	First	FDIS	Di prossima uscita	B

ISO TR 10017:2008 BOZZA NON UFFICIALIZZATA

Table C.1 – The relationship of other ISO quality management and quality management system standards (and other deliverables) to the clauses of ISO 9001

ISO 9001 Clause No.	4	5	6	7	8	9	10
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.4, 8.5.1	9.1.2	
ISO 10002					8.2.4	9.1.2	
ISO 10003						9.1.2	
ISO 10004						9.1.1	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.4.4		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.4			
ISO/TR 10013				7.5.1			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	

NOTE Where specific sub-clauses have not been cited, and instead "All" has been shown, then this indicates that all the sub-clauses to that particular ISO 9001 clause are related to the cross referenced standard.

ISO TR 10017:2003

Quadro sintetico degli usi potenziali di tecniche statistiche per adempiere quanto indicato dalle clausole di ISO 9001:2000

ISO 9001: 2000	TITOLO	Statistica descrittiva	DOE (progetto degli esperimenti)	Prova di Ipotesi statistica	Analisi delle misure	Analisi di Capacità di processo	Analisi di regressione	Analisi di Affidabilità	Campionamento	Simulazione	Carte di controllo e SPC	An.statistica delle tolleranze
0 ÷ 4												
5	**Responsabilità della Direzione**	X							X		X	
5.2	Attenzione focalizzata al cliente							X	X			
5.4	Pianificazione della Qualità											
5.6	Riesame del Sistema di Gestione per la Qualità	X		X					X			
6	**Gestione delle Risorse**	X										
6.3	Addestramento, consapevolezza e competenza	**T U T T E**										
7	**Realizzazione del prodotto**											
7.1	Pianificazione							X	X			
7.2	Processi relativi al cliente	X			X	X		X				X
7.3	Progettazione e sviluppo	X	X	X	X	X	X	X	X	X	X	X
7.4	Approvvigionamento	X		X		X			X		X	
7.5	Produzione ed erogazione di servizi	X		X		X	X	X	X		X	
7.6	Gestione dei dispositivi di monitoraggio e misurazione	X			X	X			X		X	
8	**Misurazioni, Analisi e Miglioramento**											
8.1	Generalità	**T U T T E**										
8.2	Monitoraggi e misurazioni	X		X					X			
8.3	Gestione dei prodotti non conformi	X										
8.4	Analisi dei dati	**T U T T E**										
8.5	Miglioramento	**T U T T E**										

ISO/TR 10017:2003

Contents

da ISO/TR 10017:2004 **Table 1 —**

Needs involving quantitative data and supporting statistical technique(s)

Esempio di una pagina, su un totale di 34 punti della Norma elencati

Clause/subclause of ISO 9001:2000	Needs involving the use of quantitative data	Statistical technique(s)
7.3.7 Control of design and development changes	Need to evaluate, verify and validate effect of design changes	Descriptive statistics; design of experiments; hypothesis testing; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling; simulation
7.4 Purchasing		
7.4.1 Purchasing process	Need to ensure that purchased product conforms to specified purchase requirements	Descriptive statistics; hypothesis testing; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling
	Need to evaluate suppliers ability to supply product to meet organizations requirements	Descriptive statistics; design of experiments; process capability analysis; regression analysis; sampling
7.4.2 Purchasing information	None identified	
7.4.3 Verification of purchased product	Need to establish and implement inspection and other activities to ensure that purchased product meets specified requirements	Descriptive statistics; hypothesis testing; measurement analysis; process capability analysis; reliability analysis; sampling
7.5 Production and service provision		
7.5.1 Control of production and service provision	Need to monitor and control production and service activity	Descriptive statistics; measurement analysis; process capability analysis; regression analysis; reliability analysis; sampling; SPC charts; time series analysis
7.5.2 Validation of processes for production and service provision	Need to validate, monitor, and control processes whose output cannot be readily measured	Descriptive statistics; process capability analysis; regression analysis; sampling; SPC charts; time series analysis
7.5.3 Identification and traceability	None identified	
7.5.4 Customer property	Need to verify characteristics of customer property	Descriptive statistics; sampling
7.5.5 Preservation of product	Need to monitor the effect of handling, packaging and storage on product quality	Descriptive statistics; regression analysis; reliability analysis; sampling; SPC charts; time series analysis
7.6 Control of monitoring and measuring devices	Need to ensure that monitoring and measurement process and equipment is consistent with requirement.	Descriptive statistics; measurement analysis; process capability analysis; regression analysis; sampling; SPC charts; statistical tolerancing; time series analysis
	Need to assess the validity of previous measurements, where required	Descriptive statistics; hypothesis testing; measurement analysis; regression analysis; sampling; statistical tolerancing; time series analysis
8 Measurement, analysis and improvement		
8.1 General	None identified	
8.2 Monitoring and measurement		
8.2.1 Customer satisfaction	Need to monitor and analyse information pertaining to customer	Descriptive statistics; sampling

BIBLIOGRAFIA della ISO /TR 10017

ISO publications related to statistical techniques

[1] ISO 2602:1980, *Statistical interpretation of test results — Estimation of the mean — Confidence interval*

[2] ISO 2854:1976, *Statistical interpretation of data — Techniques of estimation and tests relating to means and variances*

[3] ISO 2859-0:1995, *Sampling procedures for inspection by attributes — Part 0: Introduction to the ISO 2859 attribute sampling system*

[4] ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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[6] ISO 2859-3:1991, *Sampling procedures for inspection by attributes — Part 3: Skip-lot sampling procedures*

[7] ISO 2859-4:2002, *Sampling procedures for inspection by attributes — Part 4: Procedures for assessment of declared quality levels*

[8] ISO 3207:1975, *Statistical interpretation of data — Determination of statistical tolerance interval*

[9] ISO 3301:1975, *Statistical interpretation of data — Comparison of two means in the case of paired observations*

[10] ISO 3494:1976, *Statistical interpretation of data — Power of tests relating to means and variances*

[11] ISO 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

[12] ISO 3534-2:1993, *Statistics — Vocabulary and symbols — Part 2: Statistical quality control*

[13] ISO 3534-3:1999, *Statistics — Vocabulary and symbols — Part 3: Design of experiments*

[14] ISO 3951:1989, *Sampling procedures and charts for inspection by variables for percent nonconforming*

[15] ISO 5479:1997, *Statistical interpretation of data — Tests for departure from the normal distribution*

[16] ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

[17] ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for determination of repeatability and reproducibility of a standard measurement method*

[18] ISO 5725-3:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method*

altri 31.....

IEC publications related to reliability analysis

[50] IEC 60050-191:1990, *International Electrotechnical Vocabulary — Chapter 191: Dependability and quality of service*

[51] IEC 60300-1:1993, *Dependability management — Part 1: Dependability programme management*

[52] IEC 60300-2:1995, *Dependability management — Part 2: Dependability programme elements and tasks*

[53] IEC 60300-3-9:1995, *Dependability management — Part 3: Application guide — Section 9: Risk analysis of technological systems*

[54] IEC 60812:1985, *Analysis techniques for system reliability — Procedure for failure mode and effects analysis (FMEA)*

[55] IEC 60863:1986, *Presentation of reliability, maintainability and availability predictions*

[56] IEC 61014:1989, *Programmes for reliability growth*

[57] IEC 61025:1990, *Fault tree analysis (FTA)*

[58] IEC 61070:1991, *Compliance test procedures for steady-state availability*

[59] IEC 61078:1991, *Analysis techniques for dependability — Reliability block diagram method*

[60] IEC 61123:1991, *Reliability testing — Compliance test plans for success ratio*

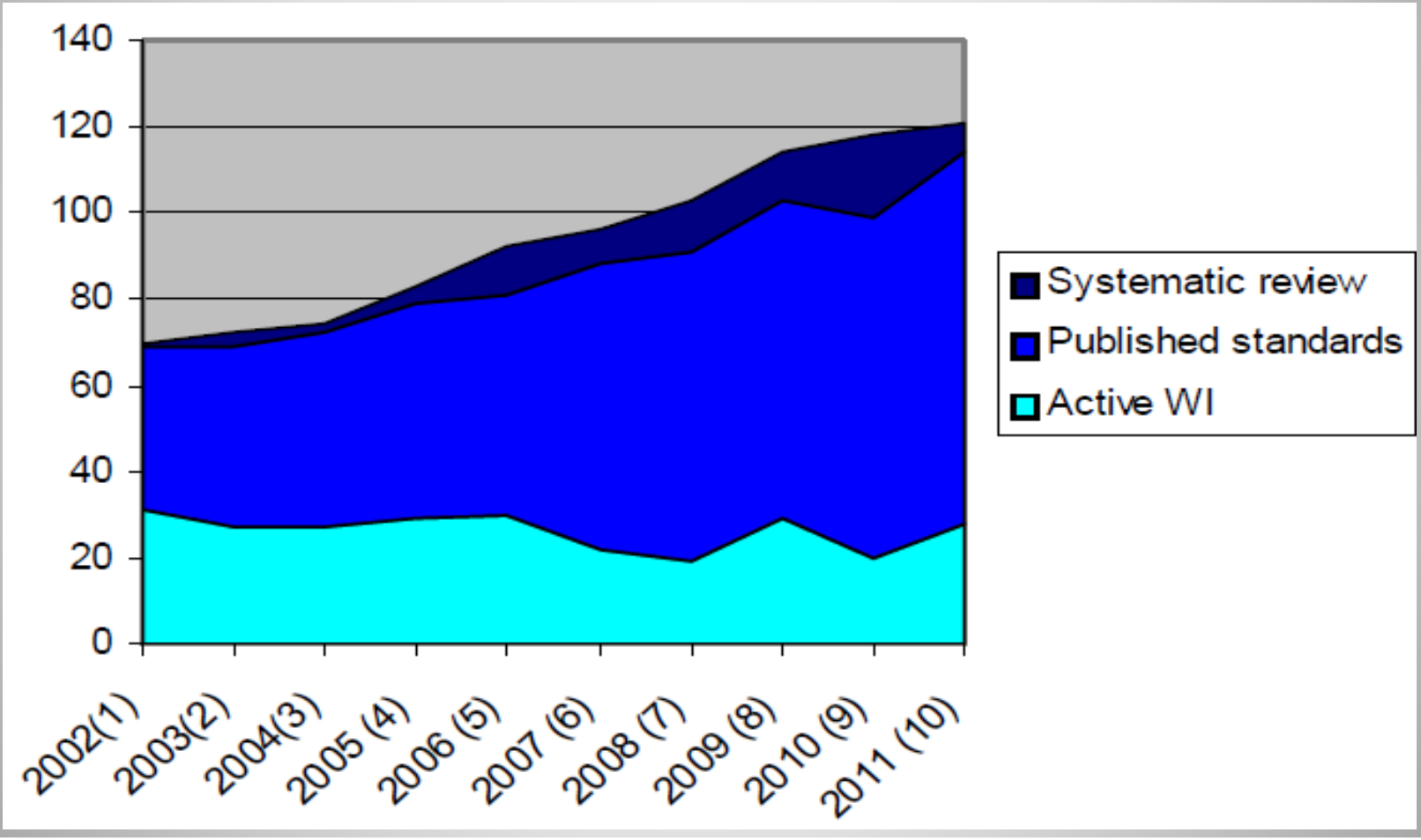
[61] IEC 61124:1997, *Reliability testing — Compliance tests for constant failure rate and constant failure intensity*

[62] IEC 61163-1:1995, *Reliability stress screening — Part 1: Repairable items manufactured in lots*

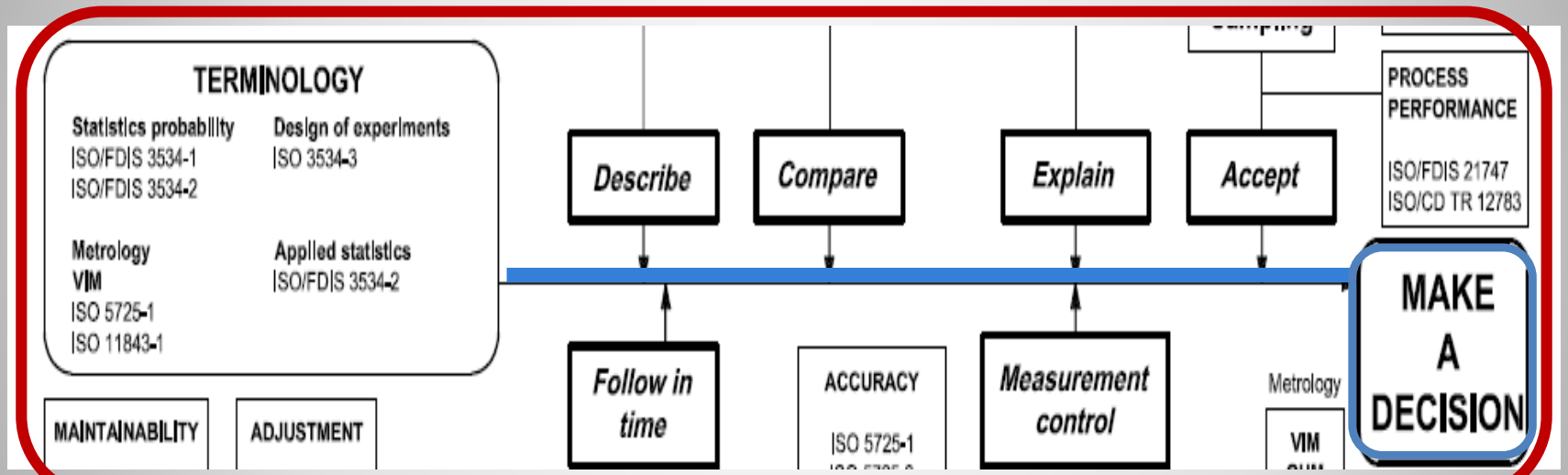
[63] IEC 61163-2: Ed 10, *Reliability stress screening — Part 2: Electronic components*

[64] IEC 61164:1995, *Reliability growth — Statistical test and estimation methods*

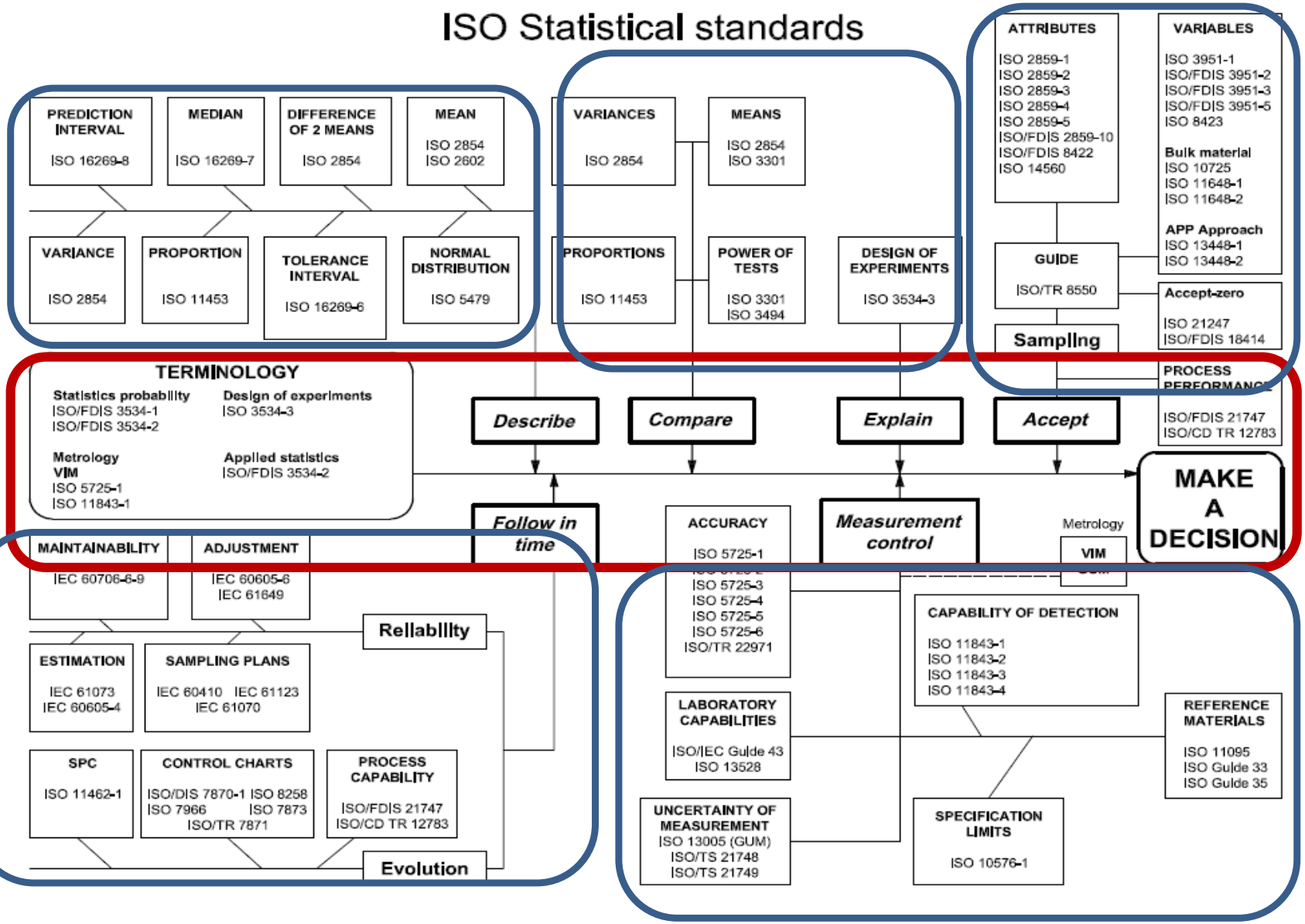
ISO TC 69 – APPLICAZIONE DI METODI STATISTICI
il corpo complessivo di norme prodotte



UNA VISIONE COMPLESSIVA DELLE NORME DEL ISO TC 69-'METODI STATISTICI E LORO APPLICAZIONI' GLI SCOPI



ISO Statistical standards



Sottocomitati del TC 69 e Numero di Norme prodotte e gestite

Subcommittee Title

- ISO/TC 69/SC 1 **Terminology and symbols** **4 STD**
- ISO/TC 69/SC 4 **Applications of statistical methods in product and process management** **15 STD**
- ISO/TC 69/SC 5 **Acceptance sampling** **25 STD**
- ISO/TC 69/SC 6 **Measurement methods and results** **32 STD**
- ISO/TC 69/SC 7 **Applications of statistical and related techniques for the implementation of Six Sigma** **11 STD**
- ISO/TC 69/SC 8 **Application of statistical and related methodology for new technology and product development** **2 STD**

TC 69/ SC7 Applications of statistical and related techniques for the implementation of Six Sigma

- ISO/TR 12845:2010
  Selected illustrations of fractional factorial screening experiments
- ISO/TR 12888:2011
  Selected illustrations of gauge repeatability and reproducibility studies
- ISO 13053-1:2011
  Quantitative methods in process improvement -- Six Sigma -- Part 1: DMAIC methodology
- ISO 13053-2:2011
  Quantitative methods in process improvement -- Six Sigma -- Part 2: Tools and techniques
- ISO/TR 13195:2015
  Selected illustrations of response surface method -- Central composite design
- ISO/TR 14468:2010
  Selected illustrations of attribute agreement analysis
- ISO/TR 16705:2016
  Statistical methods for implementation of Six Sigma -- Selected illustrations of contingency table analysis
- ISO 17258:2015
  Statistical methods -- Six Sigma -- Basic criteria underlying benchmarking for Six Sigma in organisations
- ISO 18404:2015
  Quantitative methods in process improvement -- Six Sigma -- Competencies for key personnel and their organizations in relation to Six Sigma and Lean implementation
- ISO/TR 29901:2007
  Selected illustrations of full factorial experiments with four factors
- ISO/TR 29901:2007/Cor 1:2009

ISO/TC 69/SC 8 - Application of statistical and related methodology for new technology and product development

Standard and/or project	Stage	ICS
ISO 16336:2014 Applications of statistical and related methods to new technology and product development process -- Robust parameter design (RPD)	60.60	03.120.30
ISO 16355-1:2015 Application of statistical and related methods to new technology and product development process -- Part 1: General principles and perspectives of Quality Function Deployment (QFD)	60.60	03.120.30

BIBLIOGRAFIA della ISO /TR10017

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[1] ISO 2602:1980, *Statistical interpretation of test results — Estimation of the mean — Confidence interval*

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[55] IEC 60863:1986, *Presentation of reliability, maintainability and availability predictions*

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[61] IEC 61124:1997, *Reliability testing — Compliance tests for constant failure rate and constant failure intensity*

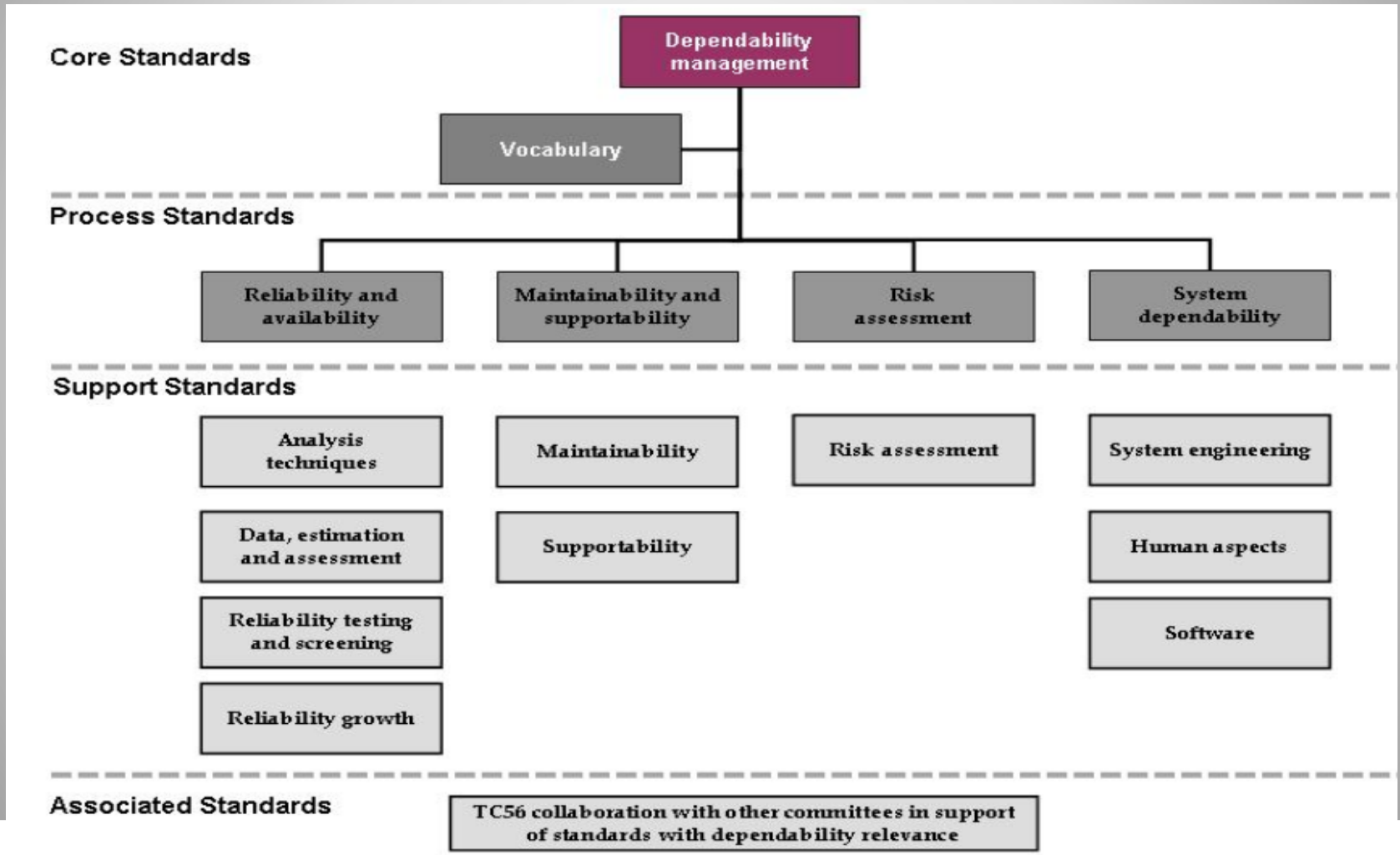
[62] IEC 61163-1:1995, *Reliability stress screening — Part 1: Repairable items manufactured in lots*

[63] IEC 61163-2: Ed 10, *Reliability stress screening — Part 2: Electronic components*

[64] IEC 61164:1995, *Reliability growth — Statistical test and estimation methods*

IEC TC 56 Dependability (Fidatezza)

IEC TC56 DEPENDABILITY- 59 Norme emesse e gestite



Termini essenziali

- **dependability,** <of an item> *ability to perform as and when required* (fidatezza)
- **reliability**, <of an item> *ability to perform as required, without failure, for a given time interval, under given conditions* (affidabilità)
- **maintainability**, <of an item> *ability to be retained in, or restored to a state to perform as required, under given conditions of use and maintenance* (manutenibilità)
- **supportability,** <of an item> *ability to be supported to sustain the required availability with a defined operational profile and given logistic and maintenance resources* (supportabilità-?)
- **availability,** <of an item> *ability to be in a state to perform as required* (disponibilità)

Dependability Standards and Supporting Standards (ora 66)

- **1. Core standards**
  - 1.1 Dependability management
  - 1.2 Vocabulary
- **2. Process standards**
  - 2.1 Reliability and availability
  - 2.2 Maintainability and supportability
  - 2.3 Risk assessment
  - 2.4 System dependability
- **3. Support standards**
  - 3.1.1 Reliability and availability - Analysis techniques
  - 3.1.2 Reliability and availability - Data estimation and assessment
  - 3.1.3 Reliability and availability - Reliability testing and screening
  - 3.1.4 Reliability and availability - Reliability growth
  - 3.2.1 Maintainability and supportability - Maintainability
  - 3.2.2 Maintainability and supportability - Supportability
  - 3.3.1 Risk assessment - Risk assessment support
  - 3.4.1 System dependability - System engineering
  - 3.4.2 System dependability - Human aspects
  - 3.4.3 System dependability - Software
- **4. Associated standards**
  - 4.1 Associated IEC standards with dependability relevance
  - 4.2 Associated ISO standards with dependability relevance

Cat.	n. norme
1.1	1
1.2	3
2.1	1
2.2	5
2.3	3
2.4	3
3.1.1	8
3.1.2	9
3.1.3	12
3.1.4	3
3.2.1	3
3.2.2	3
3.3.1	1
3.4.1	7
3.4.2	1
3.4.3	2
4.1	0
4.2	16

CENNO ALLE NORME PRINCIPALI

LA EN IEC 60300 1 –GESTIONE DELLA FIDATEZZA

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Scheda informativa su nuove norme

EN IEC 60300-1
Dependability management
(Gestione della Fidatezza)
Part 1: Guidance for management and application
Edition 3.0: 2014

2

Struttura della NORMA

INTRODUZIONE

1 Campo di applicazione
2 Riferimenti normativi
3 Termini, definizioni e abbreviazioni
  3.1 Termini e definizioni
4 Gestione della fidatezza
  4.1 Comprendere la fidatezza
  4.2 Vantaggi della gestione della fidatezza
  4.3 Sfide nella gestione della fidatezza
5 Sistema di gestione della fidatezza
  5.1 Panoramica
  5.2 Assetti organizzativi
  5.3 Azioni gestionali
  5.4 Valutazione delle prestazioni
6 Applicazione della gestione della fidatezza
  6.1 Adattamento di un programma di fidatezza
  6.2 Analisi degli obiettivi e delle prescrizioni
  6.3 Gestione dei rischi
  6.4 Realizzazione delle attività di fidatezza nel corso del ciclo di vita
  6.5 Scelta degli strumenti e delle attività tecniche per la fidatezza
  6.6 Risorse
  6.7 Misura e valutazione
  6.8 Assicurazione della fidatezza
  6.9 Verifica degli esiti e delle attività della fidatezza

Allegato A (informativo) Assetti organizzativi di un sistema di gestione della fidatezza
Allegato B (informativo) Attività di un sistema di gestione della fidatezza
Allegato C (informativo) Definizione dei requisiti di un elemento
Allegato D (informativo) Struttura delle norme sulla fidatezza
Allegato E (informativo) Lista di riscontro per una verifica della fidatezza

Bibliografia

PASSI DEL PROCESSO

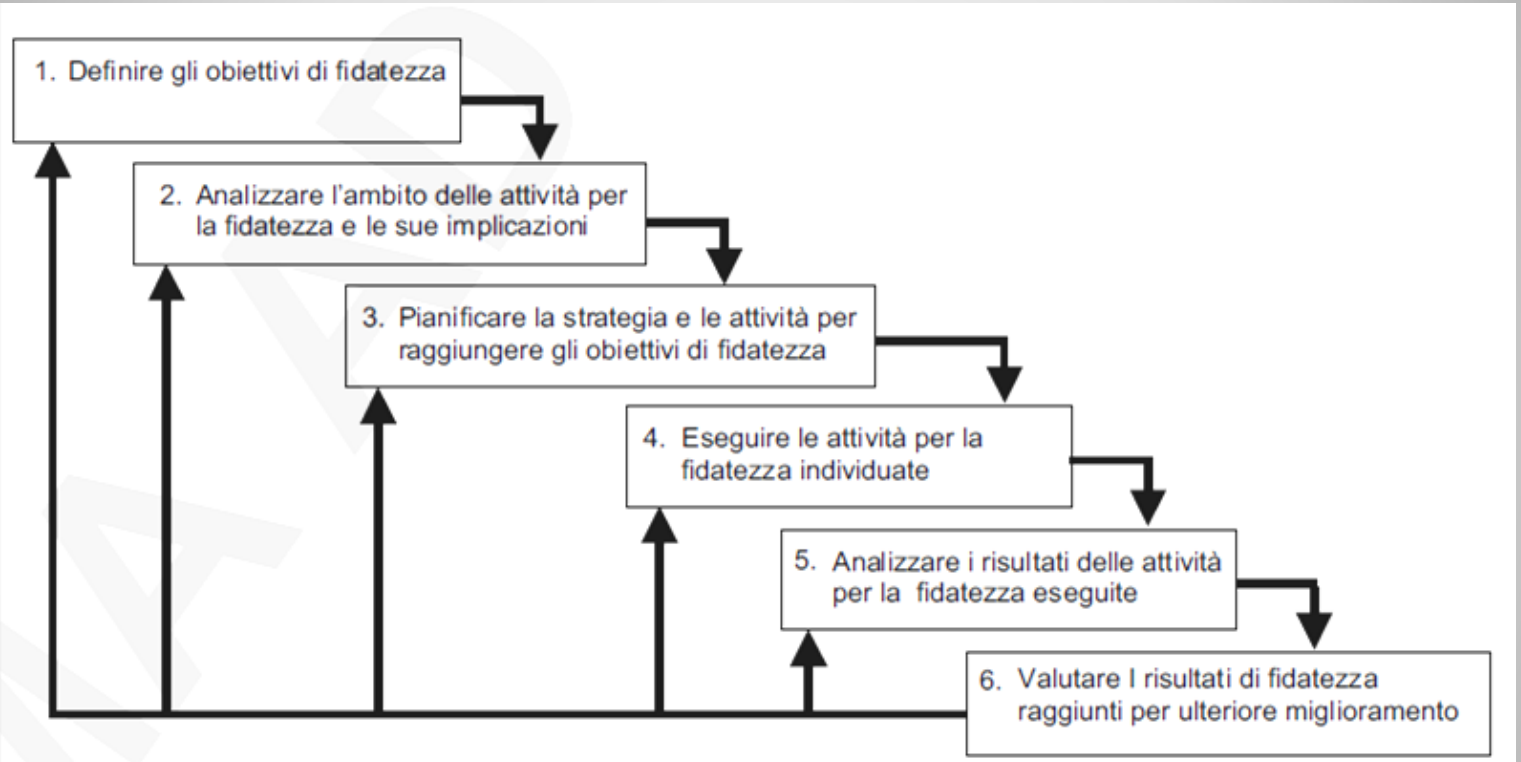

Figura 1 – Passi del processo per la gestione della fidatezza

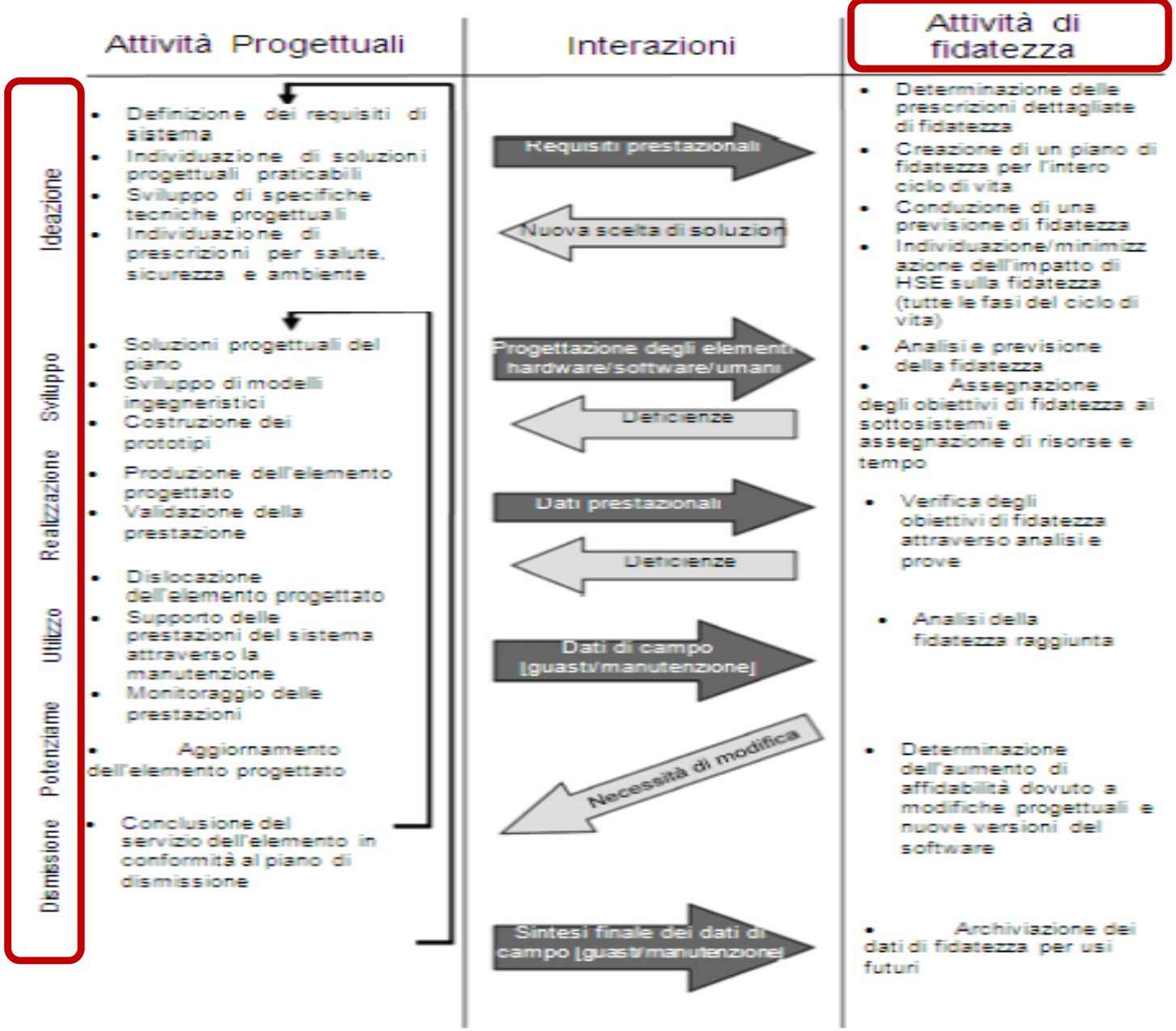

Figura B.1 – Attività di fidatezza e ciclo di vita

ATTIVITÀ PER LA FIDATEZZA, LUNGO IL CICLO DI VITA

Elementi e compiti di fidatezza	Fasi del ciclo di vita					
	C&D	D&D	MFG	INS	O&M	DIS
Elemento 1: Gestione						
Compito 1: Piani di fidatezza	xxx	xxx	xxx	xxx	xxx	xxx
Compito 2: Specifiche di fidatezza		xxx	xxx	xxx		
Compito 3: Controllo dei processi		xxx	xxx	xxx	xxx	
Compito 4: Controllo del progetto		xxx	xxx	xxx		
Compito 5: Sorveglianza e riesame		xxx	xxx	xxx	xxx	xxx
Compito 6: Gestione della catena degli approvvigionamenti			xxx	xxx	xxx	xxx
Compito 7: Introduzione del prodotto				xxx	xxx	
Elemento 2: Discipline della fidatezza						
Compito 8: Ingegneria dell'affidabilità	xxx	xxx	xxx			
Compito 9: Ingegneria della manutenibilità	xxx	xxx	xxx			
Compito 10: Ingegneria del supporto di manutenzione		xxx	xxx	xxx	xxx	
Compito 11: Standardizzazione		xxx	xxx	xxx	xxx	
Compito 12: Fattori umani	xxx	xxx	xxx	xxx	xxx	xxx
Elemento 3: Analisi, valutazione ed accertamento						
Compito 13: Analisi dell'ambiente di utilizzo	xxx	xxx	xxx			
Compito 14: Modellazione di affidabilità e simulazione	xxx	xxx	xxx			
Compito 15: Valutazione e controllo delle parti		xxx	xxx			
Compito 16: Analisi della progettazione e valutazione del prodotto		xxx	xxx			
Compito 17: Analisi di impatto (causa-effetto) e analisi del rischio		xxx	xxx	xxx	xxx	xxx
Compito 18: Previsioni	xxx	xxx	xxx			
Compito 19: Analisi di bilanciamento	xxx	xxx	xxx			xxx
Compito 20: Costo sul ciclo di vita	xxx	xxx	xxx	xxx	xxx	xxx
Compito 21: Accrescimento dell'affidabilità				xxx	xxx	

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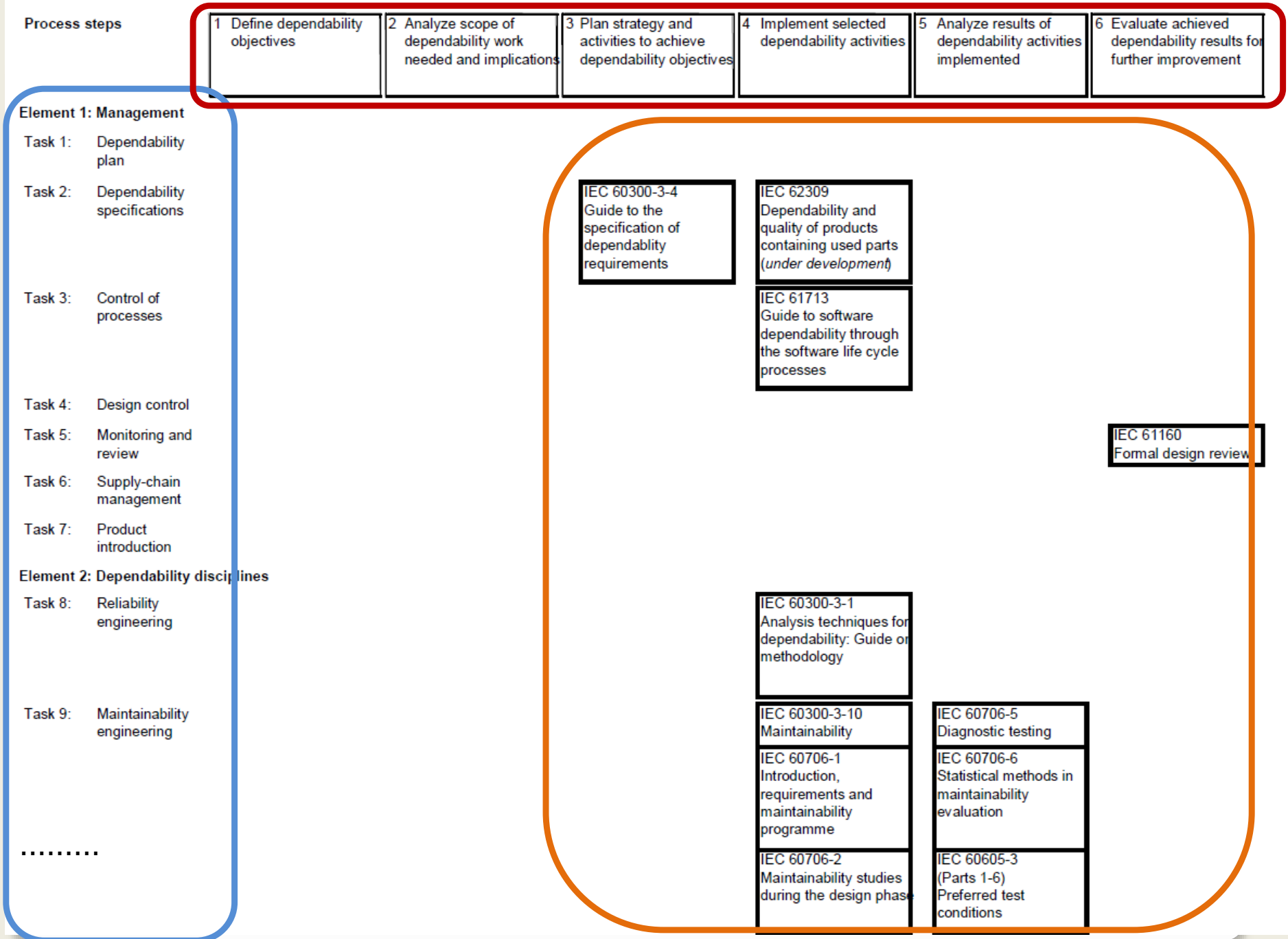

Process steps
1 Define dependability objectives
2 Analyze scope of dependability work needed and implications
3 Plan strategy and activities to achieve dependability objectives
4 Implement selected dependability activities
5 Analyze results of dependability activities implemented
6 Evaluate achieved dependability results for further improvement
Element 1: Management
Task 1: Dependability plan
Task 2: Dependability specifications
Task 3: Control of processes
Task 4: Design control
Task 5: Monitoring and review
Task 6: Supply-chain management
Task 7: Product introduction
Element 2: Dependability disciplines
Task 8: Reliability engineering
Task 9: Maintainability engineering
.....
IEC 60300-3-4 Guide to the specification of dependablity requirements
IEC 62309 Dependability and quality of products containing used parts (under development)
IEC 61713 Guide to software dependability through the software life cycle processes
IEC 61160 Formal design review
IEC 60300-3-1 Analysis techniques for dependability: Guide on methodology
IEC 60300-3-10 Maintainability
IEC 60706-5 Diagnostic testing
IEC 60706-1 Introduction, requirements and maintainability programme
IEC 60706-6 Statistical methods in maintainability evaluation
IEC 60706-2 Maintainability studies during the design phase
IEC 60605-3 (Parts 1-6) Preferred test conditions

IEC 60300-3-15 Engineering of system dependability

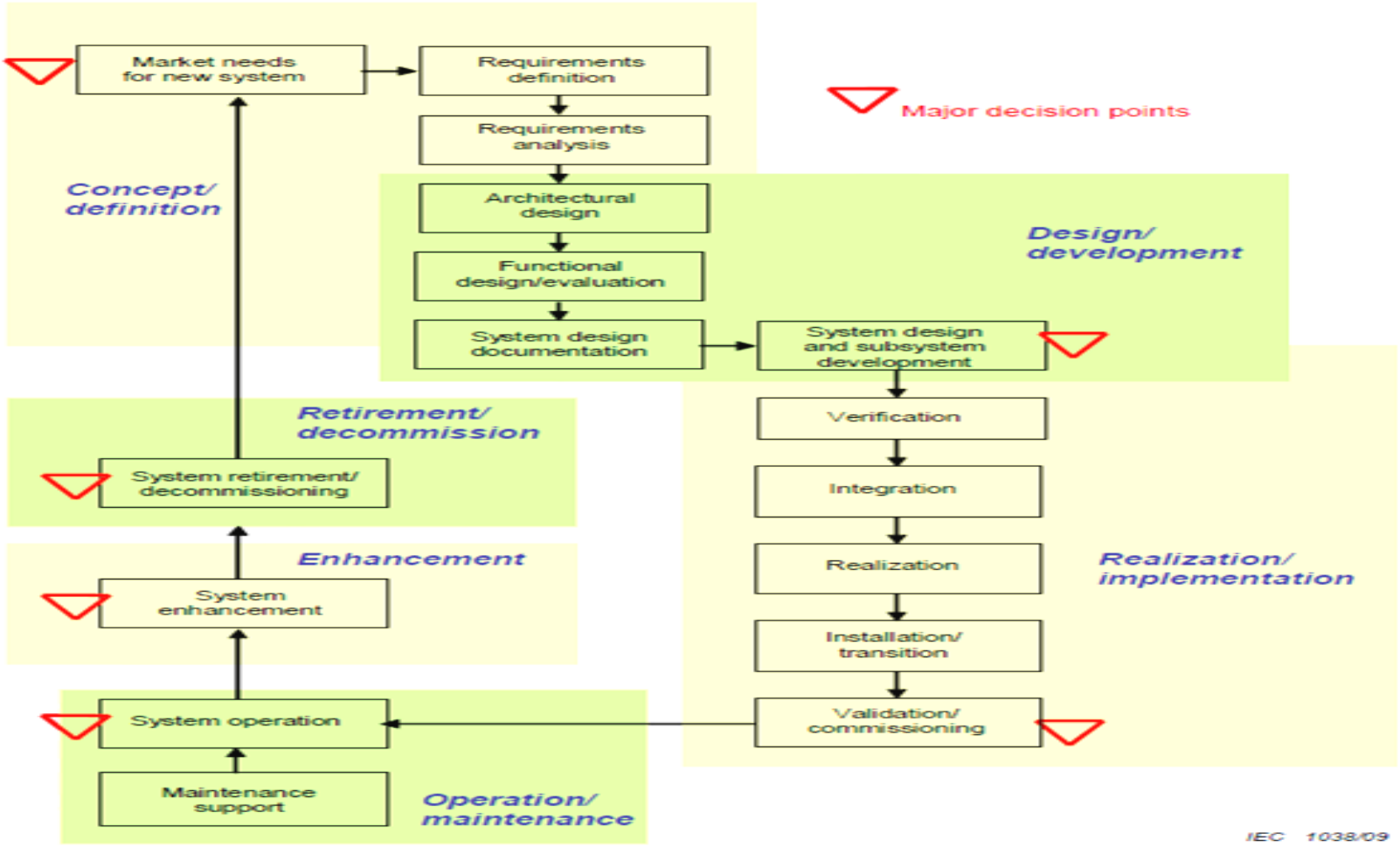


Figure A.1 – Overview of system life cycle processes

NORME PIÙ SIGNIFICATIVE DEL TC 56 IEC

- IEC 60050-192 (2015-02) IEV – Part 192: Dependability
- IEC 60300-1 (2014-05) Dependability management – Part 1: Dependability management systems
- IEC 60300-3-10 (2001-01) Dependability management – Part 3-10: Application guide – Maintainability
- IEC/ISO 31010 (2009-11) Risk management - Risk assessment techniques
- IEC 60300-3-15 (2009-06) Dependability management - Part 3-15: Application guide - Engineering of system dependability
- IEC 60812 (2006-01) Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)
- IEC 62308 (2006-07) Equipment reliability - Reliability assessment method
- IEC/TR 62380 (2004-08) Reliability data handbook - Universal method for reliability prediction of electronic components, PCBs and equipment
- IEC 60605-6 (2007-05)Equipment reliability testing – Part 6: Tests for the validity of the constant failure rate or constant failure intensity assumptions
- EC 62506 (2013-06) Methods for product accelerated testing
- IEC 61014 (2003-07) Programmes for reliability growth
- EC 60300-3-3 (2004-07) Dependability management – Part 3: Application guide – Section 3: Life cycle costing
- IEC 60300-3-4 (2007-09) Dependability management – Part 3: Application guide – Section 4: Guide to the specification of dependability requirements
- EC 61160 (2005-09) Design review
- EC 62347 (2006-11) Guidance on system dependability specifications
- IEC 62508 (2010-06) Guidance on human aspects of dependability

CENNI A NORME SPECIFICHE

LA TL 9000

TL 9000:2016 (R6)
La ISO 9001 per le TLC

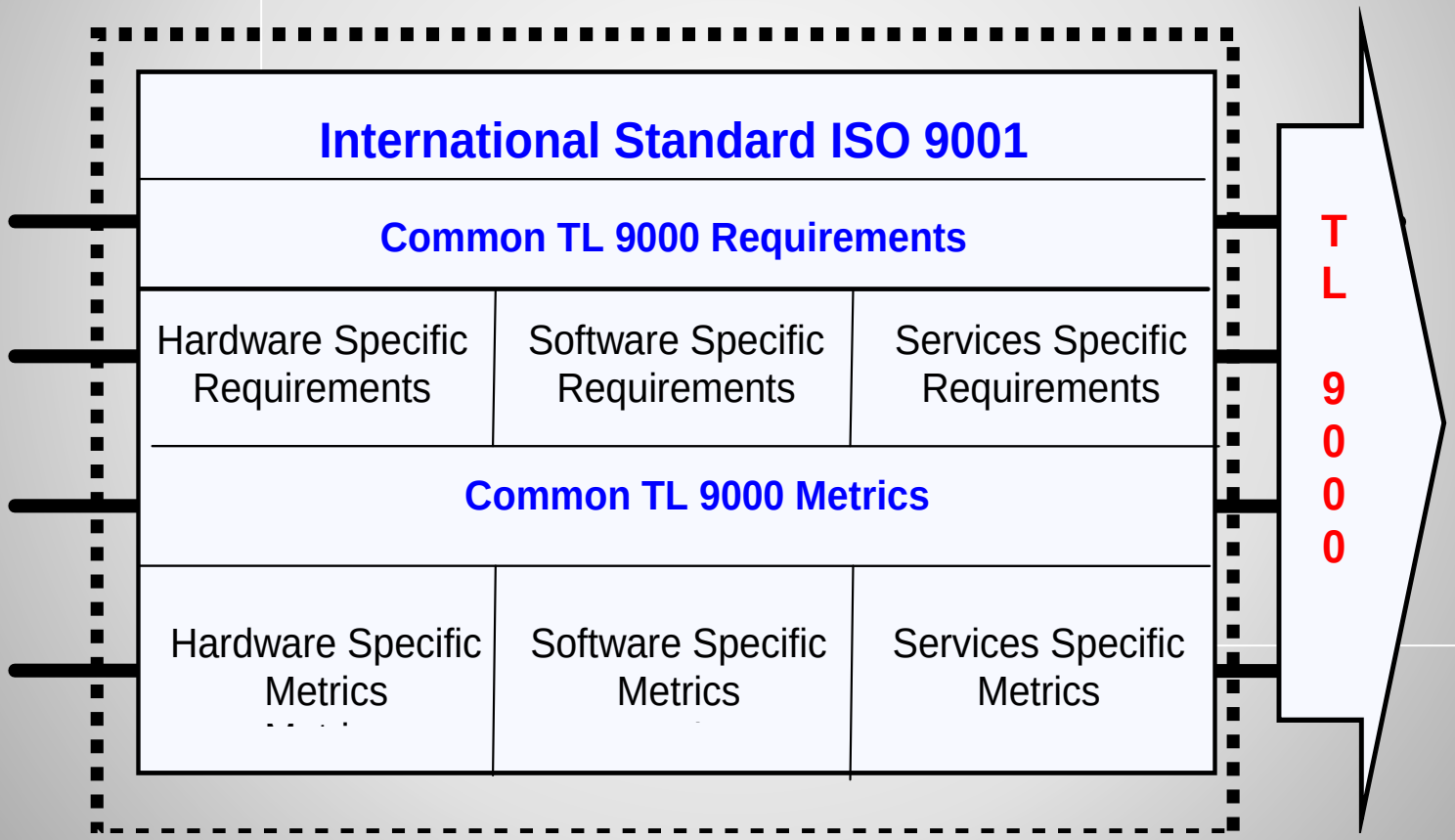
Non è una norma dell'IEC

QuEST Forum's TL 9000 standard IS THE ICT INDUSTRY'S UNIQUE EXTENSION TO ISO 9001 AND INCLUDES SUPPLEMENTAL REQUIREMENTS IN THE FOLLOWING AREAS:

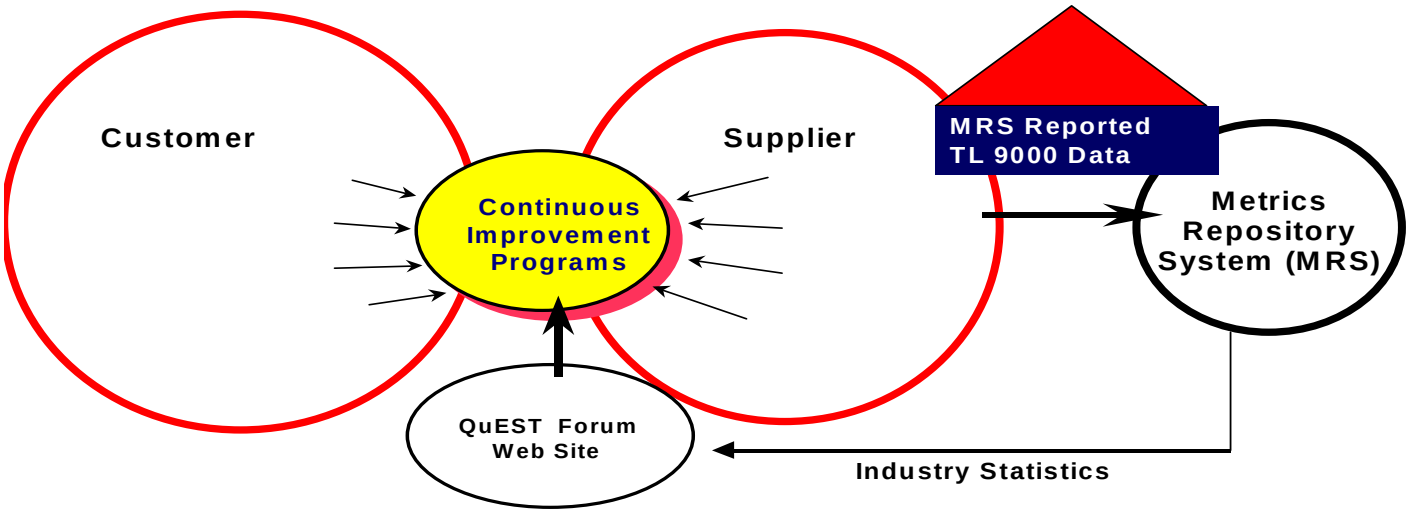
- Performance measurements based on reliability of product
- Software development and life-cycle management
- Requirements for specialized service functions such as installation and engineering
- Requirements to address communications between telecom network operators and suppliers
- Reporting of quality measurement data to a central repository

TL 9000 is a two-part quality system with significant management *and* measurement components.

TL 9000:2016 (R6)
La ISO 9001 per le TLC



TL 9000:2016 (R6)
La ISO 9001 per le TLC



Performance measurements based on reliability of product

- Software development and life-cycle management
- Requirements for specialized service functions such as installation and engineering
- Requirements to address communications between telecom network operators and suppliers
- Reporting of quality measurement data to a central repository TL 9000 is a two-part quality system with significant management and measurement components.

Publication of the TL 9000 Requirements Handbook:2016 (R6) in July 2016. http://www.questforum.org/tl90002016handbooksavailable/

CENNI A NORME SPECIFICHE

LA ISO 13053

NORME UNI ISO SU 6 SIGMA

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Scheda informativa su nuove norme

La Norma ISO 13053-1 Ed. 1-2012

Metodi quantitativi per il miglioramento dei processi- Sei Sigma

Quantitative methods in process improvement - Six Sigma -
Parte 1:DMAIC methodology

Per conto di AICQ CN[1] - Autore Giovanni Mattana - V. Presidente AICQ CN –Presidente della Commissione UNI 'Gestione per la Qualità e Metodi Statistici'

Peculiarità delle Norma

La ISO 13053, ***Quantitative methods in process improvement- Six* Sigma** consiste delle seguenti parti:

- ***ISO 13053- Part 1: DMAIC methodology***
- ***ISO 13053- Part 2: Tools and techniques***

Questa ISO 13053-1 descrive la metodologia nota come ***Sei Sigma*** che ha come scopo il miglioramento delle organizzazioni .

La metodologia tipicamente comprende cinque fasi: *define, measure, analyse, improve and control* (DMAIC).

Questa parte della ISO 13053 raccomanda *le prassi migliori o quelle preferite* da utilizzare per ciascuna delle fasi della metodologia DMAIC usata durante la attuazione di un progetto sei sigma.

La norma descrive *i ruoli e le competenze e l'addestramento del personale* coinvolto in tali progetti.

È applicabile a organizzazioni che fanno uso di processi manifatturieri come pure a processi relativi ai servizi o ai processi transazionali.

La Bibliografia richiama la iso 9000, la iso 9001, la iso 9004, la iso 21.500 sul project management,

La ISO 13053-1 è stata preparata dal Technical Committee ISO/TC 69, *Applications of statistical methods, Subcommittee SC 7, Application of statistical and related techniques for the implementation of Six Sigma.*

LA ISO 13053

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Metodi quantitativi per il miglioramento dei processi- Sei Sigma

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Indice

LA ISO 13053

4.5 Relationship with quality management standard ISO 9001

The quality principles outlined in the quality management system standards ISO 9000 and ISO 9001 call for factual approach to decision making, a process approach to achieving quality and the practice of continual improvement.

Six Sigma methods are powerful tools for top performance in each of these areas.

Quality comes out of an enterprise's system. Quality methods such as Six Sigma operate more effectively when they are integrated into an enterprise's operating system and processes, from market research to quality planning to process control and through to life cycle management.

An enterprise introducing Six Sigma should examine its operating systems to understand where existing processes need to be modified. The introduction of a range of methods, based on the use of data and problem-solving methods (such as DMAIC), could help improve the enterprise's operating systems. This can also help the enterprise improve the existing system continually, which is also a requirement of ISO 9001.

Companies which follow this route tend to achieve greater productivity, customer satisfaction and a sustainable competitive position in their market place.

LA ISO 13053-1

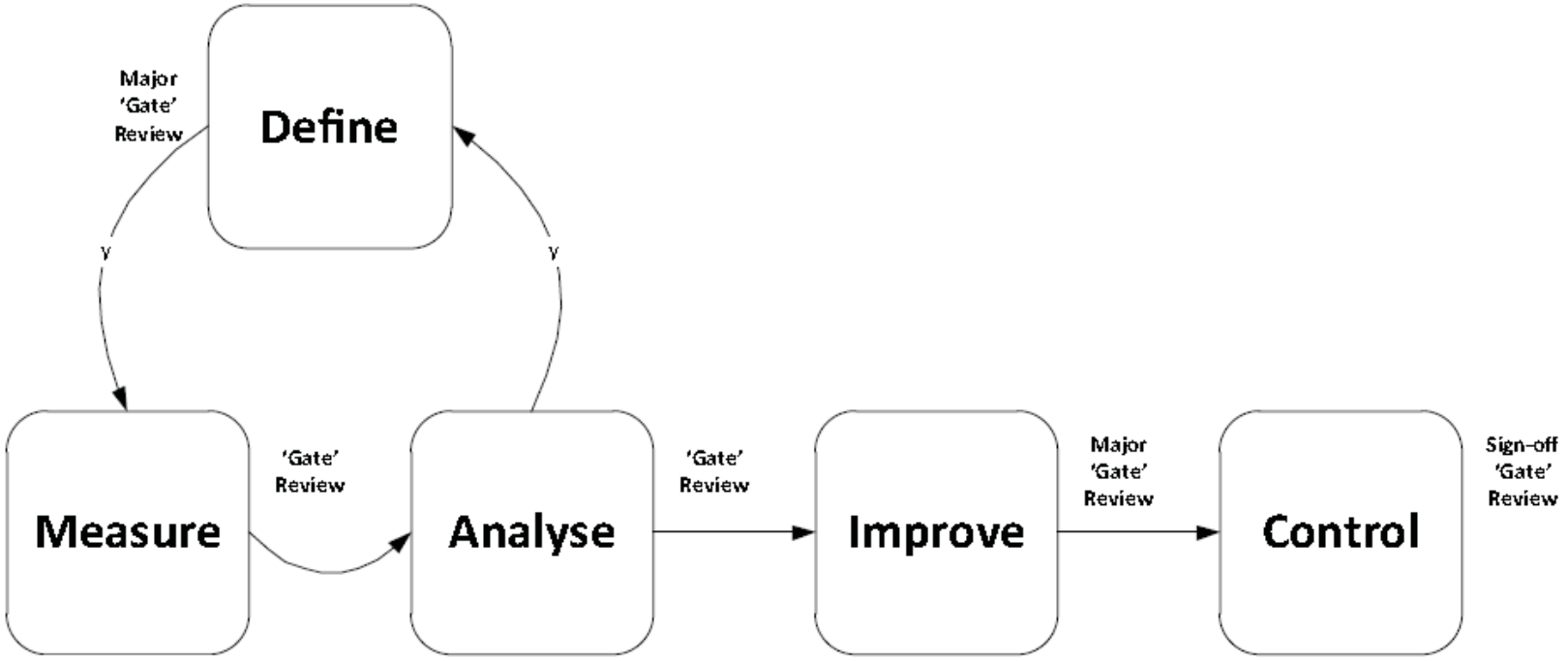

Figure 8 — Example of Six Sigma DMAIC sequence

LA ISO 13053

Table 1 — Fundamentals of Six Sigma

Question	Six Sigma phase	Description
What is the issue?	Define	Define a strategic issue to work on
Where is the process now?	Measure	Measure the current performance of the process to be improved
What is causing this?	Analyse	Analyse the process to establish the main root cause of poor performance
What can be done about it?	Improve	Improve the process through testing and studying potential solutions to establish a robust improved process
How can it be kept there?	Control	Control the improved process by establishing a standardized process capable of being operated and continually improved to maintain performance over time

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Scheda informativa su nuove norme

La Norma ISO 13053-1 Ed. 1-2012

Metodi quantitativi per il miglioramento dei processi- Sei Sigma

Quantitative methods in process improvement - Six Sigma -

Parte 1:DMAIC methodology

Table 6 (*continued*)

Tool (technique)	Fact sheet number[a]	Define	Measure	Analyse	Improve	Control
Affinity diagram	02			S		
ANOVA	24, 26			R	R	
C&E diagram	12			R		
DOE	26			R	R	
Hypothesis tests	24			R	R	
Process FMEA	14			R	M	
Regression and correlation	25			R	R	
Reliability	27			R	R	
5-why analysis	—			S		
Brainstorming	13				S	
MCA	—				S	
Mistake proofing (poka yoke)	29				R	R
Solution selection	11				R	
TPM	27				S	S
5S	29				S	S
Control plan	29					M

[a] Fact sheets are given in ISO 13053-2.

NOTE M – Mandatory; R – Recommended; S – Suggested.

LA ISO 13053-2

Scheda informativa su nuove norme

La Norma ISO 13053-2 Ed. 1-2012

Metodi quantitativi per il miglioramento dei processi- Sei Sigma

(Quantitative methods in process improvement - Six Sigma -

Parte 2: Tools and techniques

Per conto di AICQ CN[1] - Autore Giovanni Mattana - V. Presidente AICQ CN –Presidente della Commissione UNI per Sistemi Qualità e metodi Statistici

NOTA. La norma sarà pubblicata da UNI in lingua italiana nel prossimo futuro

Scopo.

Questa seconda parte della ISO 13053 descrive gli strumenti e le tecniche da utilizzare in ciascuna fase dell'approccio; ogni tecnica viene illustrata in specifica scheda.
La metodologia presentata nella Part 1 di ISO 13053 ha validità generale, indipendente dai settori economici o industriali. Ciò rende gli strumenti e le tecniche descritti in questa norma applicabili in ogni settore di attività e in ogni dimensione di business, con l'intento di guadagnare un vantaggio competitivo.

Indice

LA ISO 13053-2

Annex A (informativo) Schede

Scheda 01 — ROI, costs and accountability

Scheda 02 — Affinity diagram

Scheda 03 — Kano model

Scheda 04 — CTQ tree diagram

Scheda 05 — House of quality

Scheda 06 — Benchmarking

Scheda 07 — Project charter

Scheda 08 — Gantt chart

Scheda 09 — SIPOC

Scheda 10 — Process mapping and process data

Scheda 11 — Prioritization matrix

Scheda 12 — Cause and effect diagram

Scheda 13 — Brainstorming

Scheda 14 — Failure mode and effects analysis (FMEA)

Scheda 15 — Measurement system analysis (MSA)

Scheda 16 — Data collection plan

Scheda 17 — Determination of sample size

Scheda 18 — Normality testing

Scheda 19 — Descriptive statistics visualization tools

Scheda 20 — Indicators

Scheda 21 — Waste analysis

Scheda 22 — Value stream analysis (VSM)

Scheda 23 — Services delivery modelling

Scheda 24 — Hypothesis testing

Scheda 25 — Regression and correlation

Scheda 26 — Design of experiments (DOE)

Scheda 27 — Reliability

Scheda 28 — RACI competencies matrix

Scheda 29 — Monitoring / control plan

Scheda 30 — Control charts

Scheda 31 — Project review

CENNI A NORME SPECIFICHE

ISO/TC 69/SC8

ISO/TC 69/SC 8 - Application of statistical and related methodology for new technology and product development

Standard and/or project	Stage	ICS
ISO 16336:2014 Applications of statistical and related methods to new technology and product development process -- Robust parameter design (RPD)	60.60	03.120.30
ISO 16355-1:2015 Application of statistical and related methods to new technology and product development process -- Part 1: General principles and perspectives of Quality Function Deployment (QFD)	60.60	03.120.30

CENNI A NORME SPECIFICHE

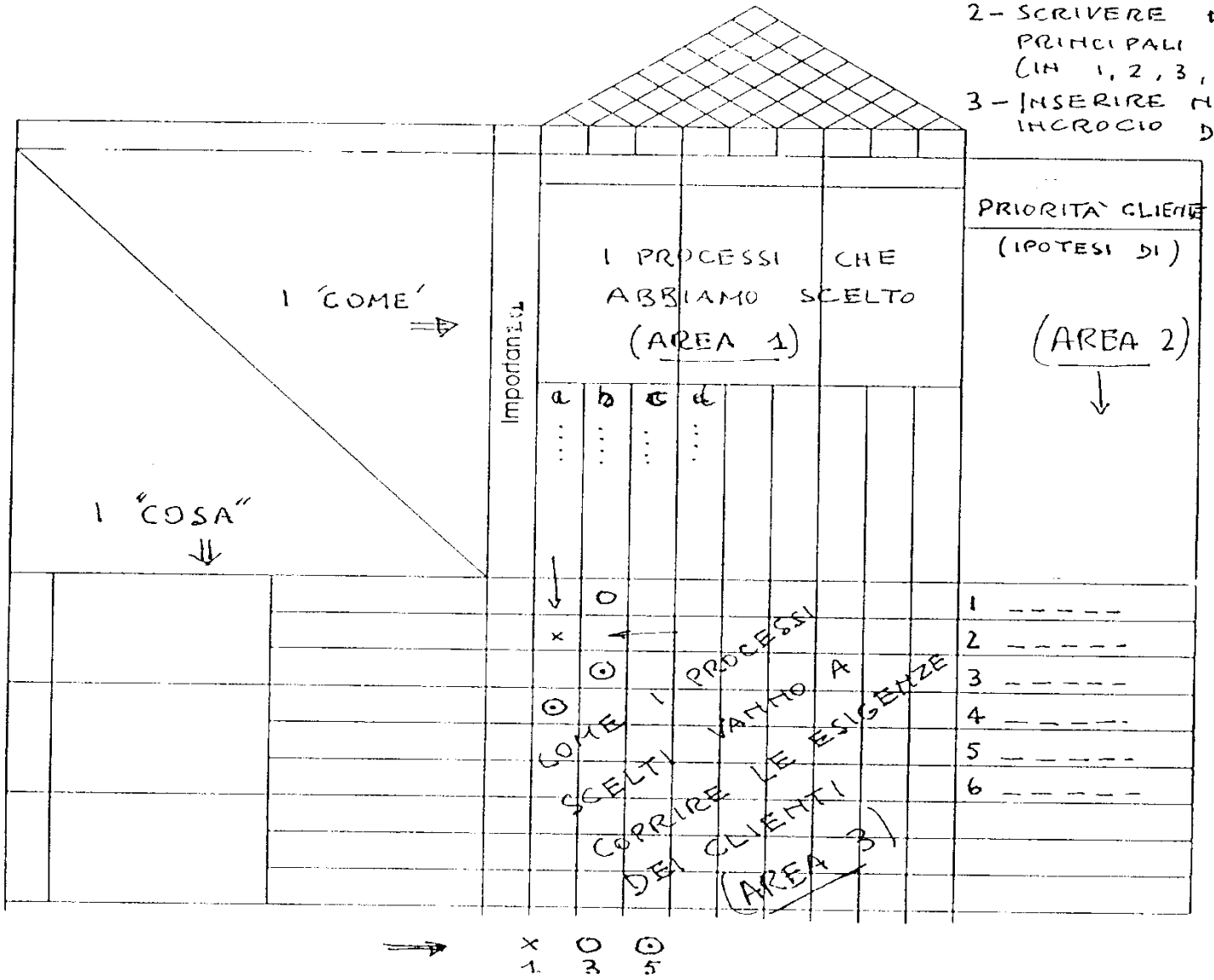
QFD

QFD ISO 16355-1

Contents

QFD ISO 16355-1

Quality Function Deployment



ESERCIZIO

1- SCRIVERE NELL'AREA 1 I PROCESSI SCELTI (in a, b, c, d)

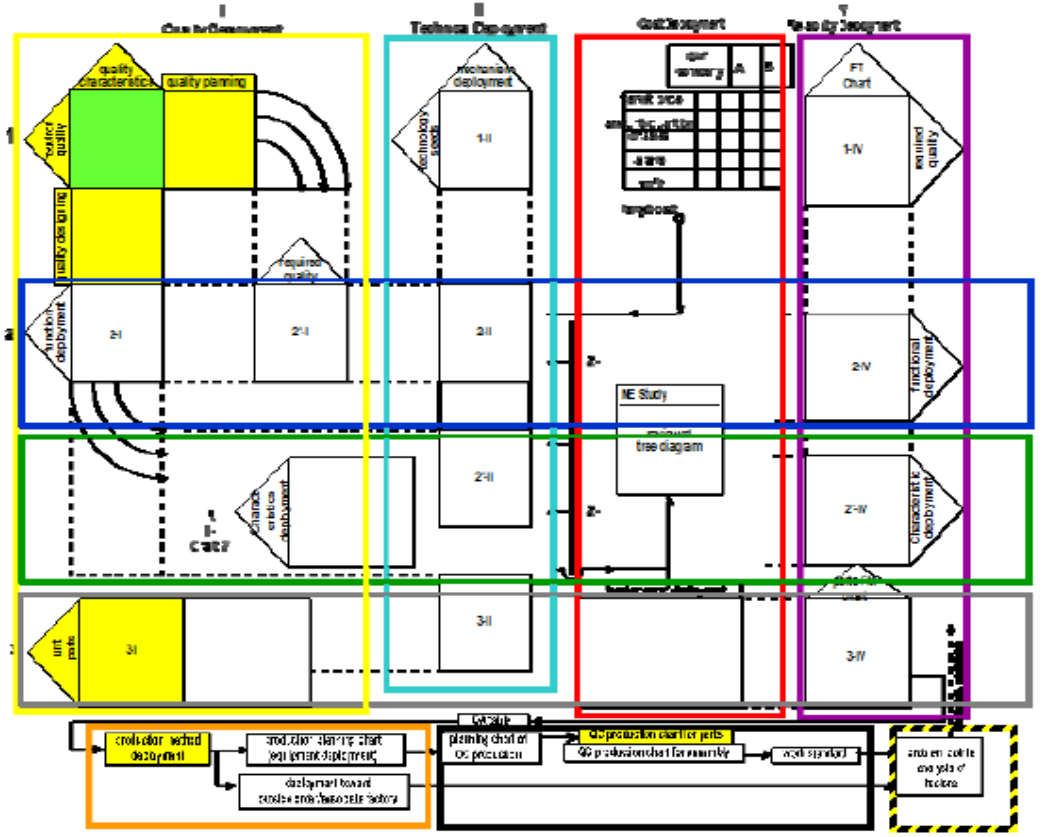
2- SCRIVERE NELL'AREA 2 LE PRINCIPALI PRIORITÀ DEL CLIENTE (IN 1, 2, 3, ...)

3- INSERIRE NEI VARI PUNTI DI INCROCIO DELL'AREA 3, IL PESO DEI SINGOLI INCROCIO TRA AREA 1 e AREA 2. IL PESO VIENE ESPRESSO DAI SIMBOLI x o ⊙

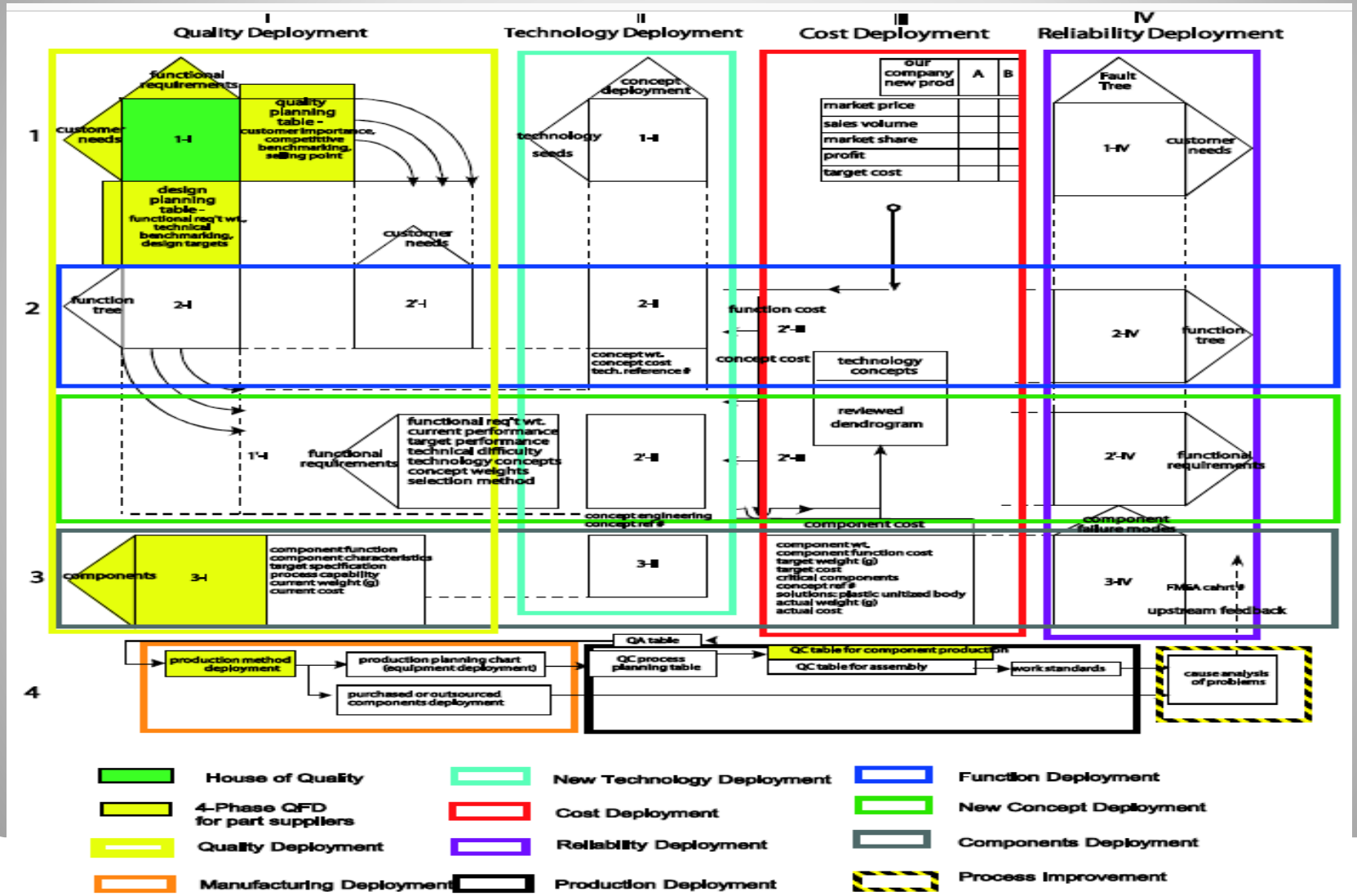
QFD ISO 16355-1

A.22 Comprehensive QFD Deployment Flow Diagram

House of Quality
4-Phase QFD for part suppliers
Quality
New Technology
Cost
Reliability
Function
New Concept
Parts
Manufacturing
Production
Process Improvement



Akao, Yoji (ed) (1988) *Quality Function Deployment: Integrating Customer Requirements into Product Design*. English translat published by Productivity Press 1990. ISBN: 0-915299-41-0


I
Quality Deployment
II
Technology Deployment
III
Cost Deployment
IV
Reliability Deployment
1
2
3
4
functional requirements
customer needs
quality planning table -
customer importance, competitive benchmarking, selling point
1-I
design planning table -
functional req't wt., technical benchmarking, design targets
customer needs
function tree
2-I
2'-I
concept deployment
technology seeds
1-II
2-II
concept wt.
concept cost
tech. reference #
our company new prod
A
B
market price
sales volume
market share
profit
target cost
function cost
2'-III
concept cost
technology concepts
reviewed dendrogram
2'-III
Fault Tree
1-IV
customer needs
2-IV
function tree
2'-IV
functional requirements
1'-I
functional requirements
functional req't wt.
current performance
target performance
technical difficulty
technology concepts
concept weights
selection method
2'-II
concept engineering
concept ref #
component cost
component failure modes
components
3-I
component function
component characteristics
target specification
process capability
current weight (g)
current cost
3-II
component wt.
component function cost
target weight (g)
target cost
critical components
concept ref #
solutions: plastic unitized body
actual weight (g)
actual cost
3-IV
FMEA cahrts
upstream feedback
production method deployment
production planning chart (equipment deployment)
purchased or outsourced components deployment
QA table
QC process planning table
QC table for component production
QC table for assembly
work standards
cause analysis of problems
House of Quality
4-Phase QFD for part suppliers
Quality Deployment
Manufacturing Deployment
New Technology Deployment
Cost Deployment
Reliability Deployment
Production Deployment
Function Deployment
New Concept Deployment
Components Deployment
Process Improvement

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ISO/PRF 16355-2 Applications of statistical and related methods to new technology and product development process -- Part 2: Acquistion of voice of customer and voice of stakeholder -- Non-quantitative approaches	50.00	03.120.30
ISO/PRF 16355-4 Applications of statistical and related methods to new technology and product development process -- Part 4: Analysis of non-quantitative and quantitative Voice of Customer and Voice of Stakeholder	50.00	03.120.30
ISO/PRF 16355-5 Applications of statistical and related methods to new technology and product development process -- Part 5: Solution strategy	50.00	03.120.30
ISO/DTR 16355-8 Applications of statistical and related methods to new technology and product development process -- Part 8: Guidelines for commercialization and life cycle	50.00	03.120.30

Una considerazione finale sui metodi quantitativi

Definizioni rilevanti, spesso quantitative

3.5.1 sistema: insieme di elementi correlati o interagenti

3.5.3 sistema di gestione: insieme di elementi correlati o interagenti di una organizzazione(3.2.1) finalizzato a stabilire politiche(3.5.8) obiettivi (3.7.1) e processi (3.4.1) per conseguire tali obiettivi

3.7.1 obiettivo: risultato da conseguire

3.7.8 prestazioni (performance): risultati misurabili

3.7.11 efficacia: grado di realizzazione delle attività pianificate e di conseguimento dei risultati pianificati

3.11.1 determinazione: attività per individuare una o più caratteristiche (3.10.1) ed I relativi valori caratteristici

3.7.9 rischio: effetto dell'incertezza

3.10.4 competenza: capacità di applicare conoscenze e abilità per conseguire i risultati attesi

3.2.3 parte interessata: persona od organizzazione che può influenzare, essere influenzata, o percepire sé stessa come influenzata, da una decisione o attività.

In gran parte richiedono di venir espressi in termini quantitativi. Se non ci sono attività e risultati pianificati (ai vari livelli significativi dell'organizzazione) non è possibile misurare l'efficacia, obiettivo fondamentale dei Sistemi di Gestione.

Definizioni rilevanti, poco conosciute, spesso quantitative ma applicate in termini qualitativi

Questo stravolgimento della lingua comporta un fondamentale stravolgimento dello spirito su cui le Norme sui Sistemi di Gestione sono costruite.

Scopo del Sistema è *CONSEGUIRE GLI OBIETTIVI.*
La parola Obiettivi (=*'risultato da conseguire'*) ricorre ora 16 volte nella Iso 9001:2015
La parola Prestazioni (=*'risultati misurabili')* ricorre ora 19 volte (nella edizione precedente erano 6 !)
La parola Efficacia (= *'grado di realizzazione delle attività pianificate e di conseguimento dei risultati pianificati'*) ricorre ora 31 volte.
E' la valutazione dell'efficacia che permette di misurare il valore aggiunto per l'organizzazione!

E il punto 6.2, Pianificazione per conseguire gli obiettivi, specifica: *Nel pianificare come conseguire i propri obiettivi per la Qualità, l'organizzazione deve determinare*
COSA sarà fatto;
QUALI RISORSE saranno richieste;
CHI ne sarà responsabile;
QUANDO sarà completato;
COME saranno valutati i risultati.

Non a caso, tra i potenziali benefici attesi da una adeguata applicazione *(vedi ISO/TC 176/SC2/N1278 Implementation Guidance),* al primo posto troviamo*:*
***'Il Focus sul RAGGIUNGIMENTO DEI RISULTATI ATTESI' (*la conformità non è l'obbiettivo, è un mezzo per ottenere gli obiettivi).**

CONCLUSIONE

- **Il SGQ è inteso non solo come base per un certificato, ma come strumento organizzativo capace di PRODURRE VALORE e DIMOSTRARE QUANTO HA PRODOTTO.**

- **Lo ribadisce il doc. Iso 176 SC2 N1276 sull'argomento 'Come dimostrare la conformità alla ISO 9001:2015': *"Per le organizzazioni interessate a ciò, è importante ricordare la necessità di fornire evidenza di una efficace implementazione del SGQ. Per richiedere conformità alla ISO 9001:2015, l'organizzazione deve essere in grado di fornire evidenza oggettiva della efficacia dei suoi processi e del suo SGQ (ottenuta tramite "osservazioni, misure, prove, o altri mezzi")."***

- **Non sembra (varie evidenze lo confermano) che questi requisiti e questa sostanza siano stati adeguatamente capiti, sostenuti, praticati; non sembra che la *forma mentis* dell'efficacia, del valore aggiunto del Sistema, e dell'importanza degli aspetti quantitativi siano stati adeguatamente assimilati.**

- **Ciò costituisce una ulteriore motivazione per una maggior diffusione ed un maggior apprezzamento dei metodi quantitativi.**

- **GRAZIE dell'ATTENZIONE!**