

**General Management Staff Operation Quality Assurance Service** 

# **QUALITY MANUAL**



## **Edition 22**

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Editorial Board University Quality Assurance Manager

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Politecnico di Milano General Management Staff Operation - Quality Assurance Service



## **Revision history**

<b>EDITION</b>	DATE	Changes	
1	01.04.1993	First issue	
2	03.04.1995	Widespread changes	
3	15.04.2000	Supplementation of UNI EN ISO 9001:1994 and UNI CEI EN 45001:1990, with references to "Vision 2000" and ISO 17025	
4	30.06.2001	Adaptation to UNI CEI EN ISO/IEC 17025:2000 and UNI EN ISO 9001:2000 (process approach and supplementation of the Politecnico Calibration Centre Quality Manual	
5	21.03.2002	Incorporation of SIT requests.	
6	04.10.2002	Extension to training activities and special teaching projects.	
7	30.01.2003	Incorporation of Italcert requests.	
8	14.10.2005	Incorporation of SIT requests	
9	12.04.2007	Transformation of CQA into QAS and overall revision of PQS	
10	June 2008	Additions as a result of 2007 Italcert and SIT third party audits (insertion of Art. 3.4) and current developments of the PQS scope of application (support services and CE marking of construction products). Insertion of Italcertifer comments for testing laboratories.	
11	22/02/2010	Adaptation to UNI EN ISO 9001:2008. Extension to orientation activities.	
12	7/06/2011	Redefinition of the University's organisational structure in view of the new management (election of new Rector, appointment of new Director General, appointment of new Management Representative, new QAS area of adherence, new Quality Policy, new accreditation body).	
13	04/04/2012	Widespread and structural changes: reissue of Quality Manual in reference to ISO 17025 and ACCREDIA requirements	
14	29/05/2012	Incorporation of ACCREDIA Testing Department requirements.	
15	20/09/2013	Incorporation of ACCREDIA Testing Department, Calibration Department, Italcert requirements, revision of reference documentation	
16	05/06/2014	Quality Policy, Sections 4.3.1, 4.8, 4.11, the rules for using the Accredia mark have been explaine in more detail, also for Italcert logo par 4.3.3. The organisation charts were inserted as annexes.	
17	23/02/2015	Section 4.14: insertion of independence criteria for carrying out audits. Insertion of changes due to LPMSC change in organisation.  Incorporation of Accredia and Italcert requirements.	
18	15/03/2016	Date consistency. Insertion of new structures adhering to the PQS (Clean Gas). Update of QAS organisation chart, update of LAB no. 1275 organisation charts. Check and update of regulatory references and incorporation of changes. Update of LAB no. 1275 figures. Update of Quality Assurance Service web reference. Reference to "Employee Code of Conduct" in relation to the values and rules of conduct for Politecnico di Milano employees.	
19	07/11/2017	Inserted the figure of LAT Centre no. 104 Deputy Manager, inserted Section 4.2.7 Suspension - self-suspension of a structure adhering to the PQS, update of current and reference standards for PQS. Inserted the certifying body for the figure of Expert Property Assessor in Section 1.1. Specified internal audit activities in more detail. Inserted new accredited structure - TextilesHUB Laboratory. Updated the references to ISO 9001:2015. Inserted definition of training effectiveness.	
20	24/10/2018	Update of LPM Organisation Chart - Updated standards of reference (in particular, the new 17025:2017), indication of the training effectiveness check, update of methods for opening and managing internal findings and internal audit findings.  Entire document: update to UNI EN ISO/IEC 17025:2018	
21	18/03/2020	February 2019 Accredia Calibrations document analysis. Definition of "technical expert". Cross management of complaints. Updated the new Quality Service structure with respect to the reorganisation of Central Administration. Update of LAT Centre no. 104 sectors.	
22	27/11/2020	Section 1.1 inserted location of structures adhering to the PQS. Update of methods to sign Accredia calibration certificates Section 7.8.4 7.8.4 Specific requirements for calibration certificates. Insertion of OCCVI organisation chart. Modification of Section 7.8.6 Formulation of declarations of conformity. Modification of Section 7.10 Non-conforming activities. Inserted ISO 17043 activities, figure of statistical expert, PT/ILC representative and strategy coordinator. Inserted Radiation Metrology Laboratory organisation chart and adjusted the fields of application of the structures. Reference to "Employee Code of Conduct" in relation to the values and rules of conduct for Politecnico di Milano employees.	



Revisio	on history	2
Quality	y Manual correlation table - standards of reference	5
0. PF	RESENTATION	9
1. SC	COPE	9
1.1.	General Information	11
2. RI	EGULATORY REFERENCES	11
3. DI	EFINITIONS AND REFERENCES	14
3.1.	3.2 Acronyms and abbreviations	15
4. Gl	ENERAL REQUIREMENTS	16
4.1.	Impartiality	16
4.2.	Confidentiality	18
5. ST	FRUCTURAL REQUIREMENTS	19
6. RI	EQUIREMENTS RELATING TO RESOURCES	32
6.1.	General information	32
6.2.	Personnel	33
6.3.	Structures and environmental conditions	36
6.4.	Equipment	37
6.5.	Metrological Traceability	41
6.6.	Externally supplied products and services	42
7. PF	ROCESS REQUIREMENTS	44
7.1.	Review of requests, offers and contracts	44
7.2.	Selection, verification and validation of methods	47
7.3.	Sampling	49
7.4.	Handling of objects subject to calibration	50
7.5.	Technical records	51
7.6.	Assessment of measurement uncertainty	51
7.7.	Assurance of validity of results	52
7.8.	Presentation of results	53
7.9.	Complaints	59
7.10.	Non-conforming activities	60
7.11.	. Control of data and information	62
8. M	IANAGEMENT SYSTEM REQUIREMENTS	63
8.1.	General information	63
8.2.	System documentation	63
8.3.	Control of quality management system documents	65



	8.4.	Control of records	69
	8.5.	Actions to address risks and opportunities	70
	8.6.	Improvement	72
	8.7.	Corrective Actions	73
	8.8.	Internal audits	74
	8.9.	Management review	75
€.	Defi	nition of processes in accordance with standard ISO 9001	75
	9.1.	Design management	77
	9.2.	Management of training and orientation activities	78
	9.3.	Management of experimental activities, testing and calibration	78
	9.4.	ANNEXES	80
	ANNE	EX 1 - Organisation Chart of Quality Assurance Service	81
	9.5.	ANNEX 2 - List of structures adhering to PQS, UNI EN ISO 9001 certified	82
	9.6.	ANNEX 3 - List of structures adhering to PQS and with Ministerial or Regional Recognition	83
	10.8	ANNEX 4 - List of structures adhering to PQS and UNI EN ISO/IEC 17025 Accreditations	84
	10.9	ANNEX 5 - List of structures adhering to PQS	89
	10.10	ANNEX 9 – Organisation Chart of the Mechanical Engineering Department	90
	10.11 Science	ANNEX 10 – Organisation Chart of the Transport Safety Laboratory - Department of Aerospa e and Technology – DSTA/LAST	
	10.12 - "G. N	ANNEX 11 - Organisation Chart of the Microstructural Analysis of Materials Service – SAM Natta" Department of Chemistry, Materials and Chemical Engineering	
	10.13 - Rese	ANNEX 12 - Organisation Chart of the Testing Lab for Materials, Buildings and Civil Structurarch Support Services Area	
	10.14	ANNEX 13 - Organisation Chart of ReLAB Laboratory	94
	10.15	ANNEX 14 - Organisation Chart of TextilesHUB Laboratory	95
	10.16 Assess	ANNEX 15 - Organisation Chart of Certification Body for the Certification of Proper	-
	10.17	ANNEX 16 - DCMC Laboratory	97
	10 18	ANNEX 17 - Radiation Metrology Laboratory	98



## **Quality Manual correlation table - standards of reference**

CHAPTERS IN THE	Reference to UNI EN ISO/IEC	Reference to UNI EN ISO 9001:2015
QUALITY MANUAL	17025:2018 ACCREDIA RT-	Reference to UNI EN 150 9001;2015
QUALITTWANUAL	08 rev. 04 and RT-25 rev. 06	
0 - Presentation	/	
1 - Scope	1 - Scope	1 – SCOPE AND FIELD OF
_ 233 <b>F</b> 3		APPLICATION
2 – Regulatory References	2 – Regulatory References	2 – REGULATORY REFERENCES
3 - Definitions and References	3 - Definitions and References	3 – TERMS AND DEFINITIONS
4 - General Requirements	4 - General Requirements	8.2.1 – Communication with the client
_	_	7.4 – Communication
		6.1 – Actions to address risks and
		opportunities
5 - Structural requirements	5 - Structural requirements	4.1 – Context of the organisation
		4.2 – Requirements and expectations of
		stakeholders
		5.1 – Leadership and commitment
		5.1.1 – General information
		5.1.2 – Focus on the client
		5.2 – Quality Policy
		5.2.1 – Establishing the Quality Policy
		5.2.2 – Communicating the Quality Policy 7.4 – Communication
		7.3 – Awareness
		7.2 - Expertise
		7.1.6 – Organisational knowledge
		5.3 – Roles, responsibilities and authority in
		the organisation
		8.1 – Planning and operational control
6 – Requirements relating to	6 - Requirements relating to	7.1 – Resources
resources	resources	8.1 – Planning and operational control
resources 6.1 - General information	resources 6.1 - General information	8.1 – Planning and operational control 7.1.1 - General information
resources	resources	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals
resources 6.1 - General information	resources 6.1 - General information	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness
resources 6.1 - General information	resources 6.1 - General information	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise
resources 6.1 - General information	resources 6.1 - General information	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge
resources 6.1 - General information	resources 6.1 - General information	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in
resources 6.1 - General information 6.2 - Personnel	resources 6.1 - General information 6.2 - Personnel	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation
resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure
resources 6.1 - General information 6.2 - Personnel	resources 6.1 - General information 6.2 - Personnel	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of
resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes
resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and
resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement
resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and environmental conditions	resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and environmental conditions	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement
resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.3 – Infrastructure
resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and environmental conditions	resources 6.1 - General information 6.2 - Personnel 6.3 - Structures and environmental conditions	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement
resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement
resources  6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.1 – Control of externally supplied
resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.1 – Control of externally supplied processes, products and services
resources  6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.4 – Control of externally supplied processes, products and services 8.4.1 – General information
resources  6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.4 – Control of externally supplied processes, products and services 8.4.1 – General information 8.4.2 – Type and extent of control
resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products and services	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products and services	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.4 – Control of externally supplied processes, products and services 8.4.1 – General information 8.4.2 – Type and extent of control 8.4.3 – Information for external suppliers
resources  6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.3 – Infrastructure 7.1.5 – Resources for monitoring and measurement 8.4 – Control of externally supplied processes, products and services 8.4.1 – General information 8.4.2 – Type and extent of control 8.4.3 – Information for external suppliers 8.1 – Planning and operational control
resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products and services  7 - Process requirements	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products and services	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.4 – Control of externally supplied processes, products and services 8.4.1 – General information 8.4.2 – Type and extent of control 8.4.3 – Information for external suppliers 8.1 – Planning and operational control 8.5 – Production and provision of services
resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products and services	resources 6.1 - General information 6.2 - Personnel  6.3 - Structures and environmental conditions  6.4 - Equipment  6.5 - Metrological traceability  6.6 - Externally supplied products and services	8.1 – Planning and operational control 7.1.1 - General information 7.1.2 – Individuals 7.3 – Awareness 7.2 – Expertise 7.1.6 – Organisational knowledge 5.3 – Roles, responsibilities and authority in the organisation 7.1.3 – Infrastructure 7.1.4 – Environment for operation of processes 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 7.1.5 – Resources for monitoring and measurement 8.4 – Control of externally supplied processes, products and services 8.4.1 – General information 8.4.2 – Type and extent of control 8.4.3 – Information for external suppliers 8.1 – Planning and operational control



CHAPTERS IN THE	Reference to UNI EN ISO/IEC	Reference to UNI EN ISO 9001:2015
QUALITY MANUAL	17025:2018 ACCREDIA RT-	Reference to CIVI EIV 150 7001.2015
QUILLI I MAINTOILE	08 rev. 04 and RT-25 rev. 06	
	001011011011111111111111111111111111111	8.2.2 – Determination of requirements
		relating to products and services
		8.2.3 – Review of requirements relating to
		products and services
		8.2.4 – Changes to requirements for products
		and services
		8.2.1 – Communication with the client
		9.1.2 – Customer satisfaction
7.2 Selection, verification and	7.2 Selection, verification and	8.3 – Design and development
validation of methods	validation of methods	8.3.1 – General information
	-	8.3.2 – Design and development planning
		8.3.3 – Design and development input
		8.3.4 – Design and development control
		8.3.5 – Design and development output
		8.3.6 – Changes to design and development
7.3 - Sampling	7.3 - Sampling	8.5.4 – Preservation
		8.5.3 – Property belonging to clients or
		external suppliers
		8.5.2 – Identification and traceability
		8.5.1 – Control of production and provision of
		services
7.4 - Handling of objects	7.4 - Handling of objects subject	8.5 – Production and provision of services
subject to calibration	to calibration	8.5.1 – Control of production and provision of
		services
		8.5.2 – Identification and traceability
		8.5.3 – Property belonging to clients or
		external suppliers
		8.5.4 – Preservation
		8.1 - Planning and operational control
7.5 – Technical records	7.5 – Technical records	8.5.1 – Control of production and provision of
		services
		7.5.3 – Control of documented information
7.6 – Assessment of	7.6 – Assessment of measurement	7.1.5 – Resources for monitoring and
measurement uncertainty	uncertainty	measurement
7.7 – Data validity assurance	7.7 – Data validity assurance	7.1.5 – Resources for monitoring and
		measurement
		8.5.1 – Control of production and provision of
		services
		9.1.3 – Analysis and assessment
		10.3 – Continuous improvement
7.8 – Presentation of results	7.8 – Presentation of results	8.6 – Release of products and services
7.8.1 – General information	7.8.1 – General information	8.5.2 – Identification and traceability
		8.5.1 – Control of production and provision of
		services
7.8.2 – Common requirements	7.8.2 – Common requirements for	8.5.2 – Identification and traceability
for reports	reports	8.5.1 – Control of production and provision of
		services
		7.5.3 – Control of documented information
7.8.3 - Specific requirements	7.8.3 - Specific requirements for	8.5.2 – Identification and traceability
for test reports	test reports	8.5.1 – Control of production and provision of
		services
		7.5.3 – Control of documented information
7.8.4 - Specific requirements	7.8.4 - Specific requirements for	8.5.2 – Identification and traceability
for certificates	certificates	8.5.1 – Control of production and provision of
		services
		7.5.3 – Control of documented information



CHAPTERS IN THE	Reference to UNI EN ISO/IEC	Reference to UNI EN ISO 9001:2015
QUALITY MANUAL	17025:2018 ACCREDIA RT-	Reference to CIVI EIV 150 7001.2015
QUILLI I MAIN CHE	08 rev. 04 and RT-25 rev. 06	
7.8.5 – Presentation of	7.8.5 – Presentation of	8.5.2 – Identification and traceability
information related to sampling	information related to sampling	8.5.1 – Control of production and provision of
7	To the second se	services
		7.5.3 – Control of documented information
7.8.6 – Formulation of	7.8.6 – Formulation of	8.5.1 – Control of production and provision of
conformity declarations	conformity declarations	services
		7.5.3 – Control of documented information
7.8.7 - Presentation of opinions	7.8.7 - Presentation of opinions	8.5.1 – Control of production and provision of
and interpretations	and interpretations	services
1	1	7.5.3 – Control of documented information
7.8.8 – Report corrections	7.8.8 – Report corrections	8.5.6 – Control of changes
	•	8.5.5 – Post-delivery activities
		7.5.3 – Control of documented information
7.9 – Complaints	7.9 – Complaints	8.2.1 – Communication with the client
*	•	8.7 – Control of non-conforming output
		10.2 – Non-conformity and corrective actions
7.10 - Non-conforming	7.10 - Non-conforming activities	8.7 – Control of non-conforming output
activities		10.2 – Non-conformity and corrective actions
7.11 – Control of data and	7.11 – Control of data and	7.5.3 – Control of documented information
information	information	7.1.6 – Organisational knowledge
8 - Management System	8 - Management System	
requirements	requirements	
8.1 – General information	8.1 – General information	7.5 – Documented information
	v	4.4 – Quality management system and related
		processes
		4.3 – Determining the field of application of
		the quality management system
8.2 – System documentation	8.2 – System documentation	7.5.1 – General requirements
		7.5 – Documented information
		7.4 – Communication
		7.1.6 – Organisational knowledge
		5.1 – Leadership and commitment
		5.1.1 – General information
		5.1.2 – Focus on the client
		5.2 - Quality Policy
		5.2.1 - Establishing the Policy
8.3 – Control of Quality	8.3 – Control of Quality	7.5.3 – Control of documented information
Management System documents	Management System documents	7.5.2 – Creation and update
		7.1.6 – Organisational knowledge
8.4 – Control of records	8.4 – Control of records	7.5.3 – Control of documented information
		7.1.6 – Organisational knowledge
8.5 – Actions to address risks	8.5 – Actions to address risks and	6.3 – Planning of changes
and opportunities	opportunities	6.1 – Actions to address risks/opportunities
		6.2 – Objectives for quality and planning to
		reach them
8.6 - Improvement	8.6 – Improvement	9.1 – Performance monitoring
		9.1.1 – General information
		9.1.2 – Customer satisfaction
		9.1.3 – Analysis and assessment
		10.1 – General information
		10.3 – Continuous improvement
8.7 – Corrective actions	8.7 – Corrective actions	10.2 – Non-conformities and corrective
		actions
8.8 – Internal audits	8.8 – Internal audits	9.2 – Internal audit
8.9 – Management review	8.9 – Management review	9.3 – Management review



CHAPTERS IN THE	Reference to UNI EN ISO/IEC	Reference to UNI EN ISO 9001:2015
QUALITY MANUAL	17025:2018 ACCREDIA RT-	
	08 rev. 04 and RT-25 rev. 06	
		9.3.1 – General information
		9.3.2 – Management review input
		9.3.3 – Management review output
		9.1 – Performance monitoring
		9.1.1 – General information
		9.1.3 – Analysis and assessment
		4.1 – Context of the organisation
		4.2 – Requirements and expectations of
		stakeholders
9 - Definition of processes in		4.4 – Quality management system and related
accordance with standard		processes
ISO 9001		4.3 – Determining the field of application of
		the quality management system
		6.2 – Objectives for quality and planning to
		reach them
		6.3 – Planning of changes
		4.1 – Context of the organisation
		4.2 – Requirements and expectations of
		stakeholders
10-Design, development and		8.3 – Design and development
management of orders		8.3.1 – General information
		8.3.2 – Design and development planning
		8.3.3 – Design and development input
		8.3.4 – Design and development control
		8.3.5 – Design and development output
		8.3.6 – Changes to design and development
		8.5 – Production and provision of services



## 0. PRESENTATION

A quality management system is the way in which an organisation (producer of goods or provider of services) defines, manages and controls its resources and activities in order to identify and satisfy the requirements and expectations of clients, providing them with a good or a service that meets the established requirements. At the same time, the organisation continuously strives to improve its performance and therefore its capacity to satisfy clients, with the guarantee that it can continuously provide those goods or services, ensuring quality and respect of the requirements and, for laboratory activities, guaranteeing impartiality, confidentiality and expertise to ensure the validity of the results.

Following the feasibility study of a quality system carried out in 1991, Politecnico prepared a system to manage multidisciplinary experimental activities in support of design, research and technological development in compliance with the requirements of European quality standards.

The experience acquired has shown that quality management is an effective tool that is also applicable to a multidisciplinary public structure such as a University, which decides to manage its activities according to the logic of process, planning, measurement and improvement.

The first Quality System was prepared based on standard UNI EN ISO 9001:1994 to reorganise management activities and UNI CEI EN 45001:1990 to plan and manage laboratory activities.

With a view to continuous improvement, in parallel with legislative changes on the European level, the Politecnico di Milano subsequently adopted a Quality Management System compliant with the requirements of standards **UNI CEI EN ISO/IEC 17025** for laboratories that carry out ACCREDIA accredited testing and/or calibration (as defined in Annex 4 of this manual) **and UNI EN ISO 9001** for ITALCERT certified testing/calibration and training activities (as defined in more detail in Annex 2 of this manual). Since its establishment, the system has been fully supported by the Rector. In 1998, the Politecnico di Milano was accredited by SIT (now Accredia Calibration Department) as Calibration Centre no. 104 (now LAT no. 104).

In 2003, the Quality Management System was extended to training activities.

In 2012, the Politecnico di Milano was accredited by Accredia Testing Department as Laboratory no. 1275.

Today, the Politecnico Quality System has been completely revised with respect to changes in the overall university system and to make it an agile working tool underlying the University's activities. This document has therefore been reworked to adapt it to legislative changes and the requirements of Accreditation and Certification Bodies. The Quality Manual and related documentary system set out the rules and criteria that the Politecnico has chosen to adopt to ensure that the activities are carried out uniformly, systematically, in a controlled manner and in compliance with the requirements of the relevant standards, with the aim of constantly improving the processes, products and services offered to internal and external clients.

The Politecnico Quality System (PQS) is managed by the Quality Assurance Service (QAS).

## 1. SCOPE

The scope of application of the Politecnico Quality Management System refers to:

- multidisciplinary experimental activities such as: testing, calibration and consulting;
- calibration activities under ACCREDIA Department of Calibration Laboratories accreditation;
- testing activities under ACCREDIA Department of Testing Laboratories accreditation;
- training activities and special projects for institutional teaching;
- testing and inspection activities aimed at the certification of construction products (CE marking);



- temperature measurements as a Notified Body in accordance with Directive 89/106/EC;
- provision of university teaching support services;
- provision of university orientation services;
- consultation for the creation of quality management systems.

The internal structures that voluntarily adopt the Quality Management System as tool to organise their activities define the specific scope of application in detail (see Annexes 2, 3, 4).

There are no exclusions to the points of standards ISO 9001 and ISO/IEC 17025 on the level of the PQS. However, with regard to services concerning the scope of application "Provision of university teaching support services", the requirement in Art. 8.3 of standard ISO 9001 is excluded since the services do not design their activities, which are based on historically defined practices and/or industry regulations/directives.

With regard to activities entrusted to external entities, each structure adhering to the PQS defines any outsourcing in view of its own scope of application. Such management excludes services provided by structures internal to the Politecnico di Milano (namely not consisting of outsourcing, for example, network management for structures relating to the Central Administration).

In recent years, the correct implementation of property assessments, following the entry into force of the European Directive on credit agreements 17/2014/EU, no longer represents just an element of prudent supervision but rather an essential element of civil discipline. This new vision and requirement of the property market and property assessment has led the Department of Civil and Environmental Engineering – DICA of the Politecnico di Milano to undertake the path of accreditation as a Certifying Body for Property Assessors according to standards UNI CEI EN ISO/IEC 17024 and UNI 11558 (for further details, see the documentation dedicated to the Certifying Body for Property Assessors - "Management System Manual").

The certification body OCCVI follows the indications contained in the relevant practice UNI/PdR 19:2016, which represents a tool for defining common rules of application in relation to the certification issued in accordance with UNI 11558.

In particular, the UNI/PdR identifies the basic elements for transparency and uniformity of the assessment and certification processes managed by accredited certification bodies in compliance with UNI CEI EN ISO/IEC 17024.

The Politecnico di Milano has undertaken the accreditation path for the activity of Proficiency Testing Organiser in accordance with standard UNI CEI E ISO/IEC 17043:2010. The first accreditation phase involves only the Energy Department - Radiation Metrology Laboratory for new proficiency tests in the field of dosimetry with a flexible field. The Politecnico di Milano will therefore become a national point of reference for such types of tests; this PT/ILC activity may also be developed for other activities in the medium term. The proficiency testing activity not only represents a new potential market development but also very prestigious activity for our laboratories, which are asked to provide an objective response to all laboratories that participate in the different organised proficiency testing methods (for further details, see the documentation dedicated to the Radiation Metrology Laboratory - "Management System Manual" LMR/MG.21.001).



#### 1.1. General Information

Politecnico di Milano

Registered office: Piazza Leonardo Da Vinci 32 - 20133 Milan University Quality Assurance Manager: Stefano Menegozzi Tel: +39 02 2399 9242 - 2055 Fax: +39 02 2399 9248

e-mail: stefano.menegozzi@polimi.it taratura@polimi.it

#### Sites of the LAT 104 Centre

Structure	City	Laboratory site
Acceleration Sector	<b>Milan</b>	Bovisa Campus - Via La Masa, 1 - 20156
Thermal Power Sector	<b>Milan</b>	Bovisa Campus - Via Lambruschini, 4a - 20156
Temperature Sector	<b>Milan</b>	Bovisa Campus - Via Lambruschini, 4a - 20156
Ionising Radiation Sector	<b>Milan</b>	Bovisa Campus - Via La Masa, 34 - 20156
Radon Sector	<b>Milan</b>	Bovisa Campus - Via La Masa, 34 - 20156
Velocity Sector	<b>Milan</b>	Bovisa Campus - Via Candiani, 72 - 20158
Flow Sector	<b>Milan</b>	Leonardo Campus - P.zza Leonardo da Vinci, 32 - 20133
Force Sector	<b>Milan</b>	Leonardo Campus - P.zza Leonardo da Vinci, 32 - 20133
Pressure Sector	Como	Como Campus - Via Anzani, 42 - 22100

#### Sites of the LAB no. 1275 laboratories

Structure	City	Laboratory site
LAST Laboratory - Passive Safety Section	<mark>Milan</mark>	Bovisa Campus - Via Durando, 10 - 20158
SAMM Laboratory	<b>Milan</b>	Leonardo Campus - Via Mancinelli, 7 - 20133
Department of Mechanical Engineering -	<mark>Milan</mark>	Bovisa Campus - Via La Masa, 1 - 20156
Laboratory	willan	Bovisa Campus - via La Masa, 1 - 20130
LPM Laboratory	<mark>Milan</mark>	Leonardo Campus - P.zza Leonardo da Vinci, 32 - 20133
ReLAB Laboratory	<b>Milan</b>	Bovisa Campus - Via Lambruschini, 4 - 20156
<b>TEXTILES HUB Interdepartmental laboratory</b>	<b>Milan</b>	Leonardo Campus - Via Ponzio, 31 - 20133
DCMIC Laboratory	<mark>Milan</mark>	Leonardo Campus - P.zza Leonardo da Vinci, 32 - 20133

#### ISO 9001 Certificate Sites

Structure	City	Laboratory site
Department of Mechanical Engineering	Milan	Bovisa Campus - Via La Masa, 34 - 20156
(laboratories)	winan	Bovisa Campus - Via La Masa, 34 - 20130
Wind Tunnel Laboratory	<mark>Milan</mark>	Bovisa Campus - Via La Masa, 34 - 20156
Machine Fluid Dynamics Laboratory	<mark>Milan</mark>	Bovisa Campus - Via La Masa, 34 - 20156
Polymer Testing Laboratory - LP3	<mark>Milan</mark>	Leonardo Campus - P.zza Leonardo da Vinci, 32 - 20133
Department of Aerospace Science and Technology	Milon	Bovisa Campus - Via La Masa, 34 - 20156
(Training activities)	Milian	Bovisa Campus - Via La Masa, 34 - 20130
<b>Energy Department (Training activities)</b>	<mark>Milan</mark>	Bovisa Campus - Via Lambruschini, 4 - 20156
Quality Assurance Service	<mark>Milan</mark>	Leonardo Campus - P.zza Leonardo da Vinci, 32 - 20133

#### 2. <u>REGULATORY REFERENCES</u>

The quality systems are subject to the following regulations of reference:

- Statute of Politecnico di Milano issued with Rector's Decree no. 623/AG of 23 February 2012 and published in Official Journal no. 52 of 2 March 2012
- Legislative Decree 81/2008 on workplace health and safety as amended and supplemented;
- Legislative Decree of 196/03 "Code on the protection of personal data" as amended and supplemented;



- Decree 9 May 2003, no.156 Criteria and methods for issuing authorisation of certification, inspection and testing bodies in the sector of construction products, in accordance with Article 9, Section 2 of Presidential Decree 21 April 1993, no. 246;
- Legislative Decree of 12 April 2006, no. 163 Code of public contracts for work, services and supplies implementing Directives 2004/17/EC and 2004/18/EC as amended and supplemented;
- UNI CEI EN ISO/IEC 17025:2018 "General requirements for the competence of testing and calibration laboratories";
- UNI EN ISO 9001:2015, Quality management systems Requirements;
- UNI CEI EN ISO/IEC 17024:2012, Conformity assessment General requirements for bodies certifying individuals;
- UNI CEI E ISO/IEC 17043:2010 "Conformity assessment General requirements for proficiency testing methods"
- ISO 13528:2015 Statistical methods for use in proficiency testing by interlaboratory comparison
- UNI 10999:2004, Guidelines for documentation of quality management systems.
- UNI EN ISO 9004:2018, Quality management systems Guidelines for enhancing performance;
- UNI EN ISO 9000:2015, Quality management systems Fundamental concepts and vocabulary;
- UNI EN ISO 19011:2018, Guidelines for management system audits;
- UNI ISO 31000:2018, Risk management Guidelines
- ISO/IEC Guide 98-3:2008, Uncertainty of measurement Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)
- ISO/IEC Guide 98-4:2008, Uncertainty of measurement Part 4: Role of measurement uncertainty in conformity assessment
- UNI CEI 70098-3:2016, "Uncertainty of measurement Part 3: Guide to the expression of uncertainty in measurement"
- UNI EN ISO 10012:2004 "Requirements for measurement processes and measuring equipment";
- UNI ISO 7870-2:2014 "Control chart Part 2: Shewhart control chart";
- JCGM 200:2008 "International vocabulary of metrology Basic and general concepts and associated terms";
- JCGM100:2008 "Evaluation of measurement data Guide to the expression of uncertainty in measurement"
- ILAC P10:01/2013 "ILAC Policy on Traceability of Measurement Results";
- ILAC P14:01/2013 "ILAC Policy for Uncertainty in Calibration";
- ILAC-G8:09/2019 Guidelines on Decision Rules and Statements of Conformity
- EA-4/02 M:2013 "Evaluation of the uncertainty of measurement in calibration";
- UNI EN ISO 10012:2004, Requirements for measurement processes and measuring equipment
- EA-4/15:2015 "Accreditation for Bodies Performing Non-Destructive Testing";
- EA-4/16:2003 "EA guidelines on the expression of uncertainty in quantitative testing";
- ACCREDIA RG-02 "Regulation for the accreditation of Test and Medical Laboratories";
- ACCREDIA RG-02-01 "Regulation for the accreditation of multisite laboratories";
- ACCREDIA RG-04 "Regulation for the operation of the Accreditation Committee":



- ACCREDIA RG-04-DL "Regulation for the operation of the Accreditation Sector Committee of the Testing Laboratories Department (CSA DL)";
- ACCREDIA RG 04-DT "Regulation for the operation of the Sector Accreditation Committee of the Calibration Laboratories Department (CSA DT)";
- ACCREDIA RG-09 "Regulation for the use of the ACCREDIA mark";
- ACCREDIA RG-13 "Regulation for the accreditation of calibration laboratories";
- ACCREDIA RT-08, General requirements for the accreditation of testing laboratories;
- ACCREDIA RT-25 "Requirements for the accreditation of calibration laboratories";
- ACCREDIA RT-36 "Requirements for the accreditation of calibration laboratories related to Interlaboratory comparisons;
- ACCREDIA DT-02-DT "Guide for the management and control of the laboratory information system";
- ACCREDIA DT-03-DT "Guide for drafting technical procedures of accredited calibration laboratories";
- ACCREDIA DT-04-DT "Rules for writing for calibration laboratories and reference material producers";
- ACCREDIA DT-05-DT "Introduction to criteria for assessing the uncertainty of calibration measurements";
- ACCREDIA DT-0002 Guide for the assessment and expression of uncertainty of measurements:
- ACCREDIA DT-0002/2 Applied examples of assessing the uncertainty of mechanical measurements;
- ACCREDIA DT-0002/5 Applied example for measurements on structural materials;
- ACCREDIA DT-0002/6 Guide for calculating the repeatability of a testing method and its verification over time;
- ACCREDIA IO-09-DT "Operating instruction for completing calibration certificates for calibration centres accredited by ACCREDIA-DT";
- ACCREDIA LS-09 "List of standards and documents of reference for the accreditation of calibration laboratories and reference material producers"
- ACCREDIA Policy on applying the requirement of metrological traceability of measurement results for calibration laboratories and reference material producers.
- ACCREDIA RT 27 Requirements for accreditation of proficiency testing programme organisers
- ACCREDIA RG 14 Regulation for the accreditation of proficiency testing programs (PTP)

All ACCREDIA and EA documentation relating to the testing and calibration activities performed by the Politecnico di Milano is kept and updated on the websites www.accredia.it, www.european-accreditation.org, www.bipm.org, www.uni.com and other sites kept by the issuing bodies.

Other reference regulations are also found on the:

- Politecnico di Milano website:
- Website of the University Library System for technical regulations.

The list of reference documents of the Politecnico di Milano Quality Management System, including those referred to by the metrology and laboratory sectors, is available online in an updated version at www.qualità.polimi.it in the intranet section.

The Quality Assurance Service (QAS) verifies the validity and traceability of the quality management system rules. For rules relating to testing and calibration methods, each local quality manager (QAM) guarantees their traceability and updating. The foregoing is specified in the "Documentation Management" procedure (QAS/MGP.07.054).



## 3. DEFINITIONS AND REFERENCES

Having ascertained that European Community Law is both constitutionally and by jurisprudence super-ordinate to that of the Member States, the terminologies expressed in international and national rules applicable to the activities performed also apply to this Manual (as cited in Ch. 2) et seq.:

Laws/Decrees These are prescriptive documents by the competent authorities with which the

Politecnico must comply in carrying out its activities.

Rules and The Rules and Regulations are internal and external prescriptive documents

Regulations with which Politecnico must comply in carrying out its activities.

Record Documents that set out the results achieved or provide evidence of the activities

documents performed.

Organisation Person entrusted the management of a laboratory or process. Politecnico organisational structure This defines the reciprocal interfaces and operating

relationships between the various functions (offices, services, departments) of

the Politecnico.

Editorial Board This does not necessarily coincide with the entity that must perform the

activities envisaged in the document. It is usually the manager of the activity or standard requirement or the figure that has expertise in the sector/subject

discussed in the document itself.

Verification This corresponds to the signature of the person responsible for verifying that the

document prepared corresponds to the management system and the standards of reference. If the verification of correspondence with a standard requires specific technical expertise, the person in charge of the verification obtains support from the specific technical figures, who also sign in the specific field. This may relate to endorsement of the hierarchical managers of the issuing structure and those

who (if they do not coincide with the issuing structure) have shared

responsibility for ensuring that the structure is aligned with the document.

Approval Those responsible for ensuring that the structure complies with the content of

the procedural document. This corresponds to the signature of those who authorise issuance of the document and actually make it effective and

prescriptive for the actions of the Politecnico.

Education Acquisition, maintenance and improvement over time of adequate training with

regard to expertise/knowledge of the area of the individual professional activities and based on the technological evolution of products, services and

markets.

Training Acquisition, maintenance and improvement over time of adequate training for

the purposes of creating new and/or improved managerial and behavioural

capacities within the company organisation.

Planning Specific activity implemented to obtain the provision of the service in coherence

with the quality policy goals, to satisfy the needs of the client and mandatory

requirements.

Contract review Systematic verification to ensure the correct expression of the basic terms of the

supply (technical contents, quantity, subject, price, payment terms and

delivery/service provision terms), the correct understanding and application of the requirements expressed by the client in the quote request, or the results of investigations performed to meet the client's needs/expectations, along with any

deviations from the quote.



Systematic examination to determine the extent to which a process or activity is Assessment

capable of satisfying the necessary requirements.

Ordinary maintenance involves regular inspection and cleaning to guarantee the **Ordinary** Maintenance

equipment, instruments or devices have the required level of performance,

reliability and safety.

Extraordinary Extraordinary maintenance is necessary as a result of malfunctions and sudden

Maintenance stops of the means used.

Monitoring Continuous control of the following conditions:

Operating and service conditions provided to the client

Timescale and quality of supplies

Adequacy and implementation of the Quality System

This is a technical activity aimed at assessing the technical performance Qualification

capacity of testing and/or calibration activities (or their phases).

These represent the non-conformities identified. Using non-conformity reports, Non-conformity the activities ensuing from the non-conformities are managed, with regard to reports

> both the treatments (and containment actions) and corrective actions necessary to prevent recurrences or to resolve situations of non-conformity that present

high risk of repetition.

Customer or Internal or external client that asks the Politecnico to perform an activity

client

Complaint Expression of dissatisfaction shown to the organisation or laboratory relating to activities or results of said laboratory or organisation and for which a response

is expected

Interlaboratory Organisation, execution and assessment of measurements or tests on the same Comparison or similar objects by two or more laboratories in accordance with established

Laboratory Body that carries out one or more phases of the following activities

tests:

calibrations;

sampling associated with subsequent tests or calibrations

Decision rule Rule that describes the way to account for measurement uncertainty when

compliance with a specified requirement is declared

## 3.1. 3.2 Acronyms and abbreviations

The acronyms and abbreviations used in this document are:

- QAS: Quality Assurance Service
- PQS: Politecnico Quality System
- QMS: Quality Management System
- LAT: Calibration Centre
- CAB: Testing Laboratory
- ACCREDIA-DT: Calibration Laboratory Department
- LM: Laboratory Managers
- SM: Metrology Sector Manager
- TTM: Testing Technical Manager
- TT: Testing Technician
- QAM: Quality Assurance Manager

Politecnico di Milano General Management Staff Operation - Quality Assurance Service



• RAFC: Regulation on Administration, Finance and Accounting

• HRO: Human Resources and Organisation

• ASICT: ICT Services

• QM: Politecnico Quality Manual

• GL: Guidelines

• MGP: Management procedures

• QPL: Quality Plan

• OPP: Operating procedures

• OPI: Operating instructions

• DOC: Documents

• FOR: Forms

• NC: Non-Conformities

• CA: Corrective Actions

• AG: Audit Group

• AGM: Audit Group Manager

## 4. GENERAL REQUIREMENTS

## 4.1. Impartiality

The Politecnico guarantees its structures the necessary independence to ensure that the requirements relating to applicable regulations are fully satisfied, avoiding conflicts of interest, and with the ability to demonstrate that the different structures and respective staff are free of undue commercial, financial or other pressures likely to have a negative influence on technical judgments. By way of its organisational structure and managerial staff, the Politecnico implements all provisions and supervision necessary to ensure that no activities are carried out that may compromise trust in the Politecnico's independence of judgment and integrity in testing, calibration, inspection, certification activities, etc. This Quality Manual outlines the fundamental requirements and guidelines with which Politecnico structures must comply.

The University organisation is based on the distinction between:

- Political Administration, which defines objectives, makes general plans and verifies achievement of the results with respect to the instructions given;
- Management, which is responsible for financial, technical and administrative management with the related responsibilities;
- Under the terms established by existing legislation and according to their respective roles, the Political Administration and Management act in synergy in the public interest and in pursuit of institutional goals.

The Political Administration managers are the Rector, Academic Senate and Board of Governors, as they are responsible. The Rector may appoint delegates or representatives on specific matters.

The Management director is the Director General, who coordinates the activities of the directors and department managers, ensuring their activities comply with the objectives and programmes of the University governing bodies, and ensuring respect for the related directives.

The Directors coordinate the operation of the offices and services of the University.

The Department Managers, Department Heads and Director General are responsible for managing the department.

The **Quality Assurance Service** (**SQuA**) is a service established in Central Administration to ensure that all structures adhering to the Politecnico Quality System (PQS), irrespective of the relevant standard to which its Certification/Accreditation refers, respect all requirements defined by the legislation, including regulations of the individual accreditation/certification bodies.

Politecnico di Milano General Management Staff Operation - Quality Assurance Service



The QAS Service is centralised and politically/financially independent from the departments to which the individual structures are subordinate.

The QAS is therefore the guarantor of the University's entire QMS and its impartiality through the preparation, dissemination and revision of all documentation. The individual structure is in charge of supplementing the administrative documentation of the structure with any technical documentation and, for laboratories, drafting specific assessments regarding the risks of impartiality within its structures.

The support provided to individual structures by the Quality Assurance Service, which guarantees the effectiveness of the QMS, is recorded by completing "logbooks" on the Quality Assurance Service webpage as well as through the exchange of emails and/or meetings to guarantee the incorporation of what is defined centrally by the QAS and any ongoing changes.

The **structures**, depending on their complexity, may appoint a local QAM to operate within the structure to manage the PQS. Any local QAMs are coordinated by the QAS and act following its indications.

The Rector has also appointed a representative in the role of **Manager of Calibration Centre LAT no. 104** to coordinate the University's activities in the field of calibration and to guarantee its scientific requirements, both regarding QAS personnel who manage the calibration jobs and those forming part of the Metrology Sectors. In particular, the Calibration Centre Manager guarantees the resources, competencies and conformity with the rules of reference for the activities performed by the Metrology Sectors and, for the Sectors accredited by ACCREDIA – DT, with the requirements of ACCREDIA – DT itself. In each sector accredited by ACCREDIA – DT, a Sector Manager is also appointed by the Department Head to perform the functions as substitute for the Manager of Calibration Centre LAT no. 104 for the size of his/her remit. This appointment and any changes are subject to the prior approval of ACCREDIA. For Metrology Sectors not accredited by ACCREDIA – DT, the Manager of Calibration Centre LAT no. 104 acts as Metrology Manager.

For all personnel at the LAT 104 Centre, the minimum requirements to cover the role are outlined in this Quality Manual and the details are included in specific documents of the laboratories that deal with the individual physical quantities. As far as possible, changes are always managed broadly in advance by way of suitable training and using internal personnel through job shadowing. The whole path of change is supervised by the QAS and all records are retained.

With regard to testing laboratories, the Rector is the **Manager of Testing Laboratory LAB no. 1275**. The individual Department Head is implicitly entrusted with the duty of coordinating laboratory activities. Interaction with Accredia DP is maintained by the ACCREDIA Representative.

At each laboratory (site), the Manager of the testing laboratory (LAB no. 1275) is appointed by the Department Head/Structure, or it may be the Head himself/herself.

The Manager relies on collaboration with the **Technical Testing Managers** who guarantee the correct conduct of the technical activities and guarantee the technical quality of the test results.

The laboratories that organise **proficiency testing** may appoint a **Laboratory Scientific Coordinator** to liaise with Accredia, acting as management, and a **Laboratory Manager** must be appointed to promote the study and feasibility of proficiency testing methods, assuming all duties attributed to the proficiency testing organiser in standard UNI CEI EN ISO/IEC 17043:2010.

The Laboratory Manager relies on collaboration with the PT/ILC Coordinator, who defines the individual proficiency testing methods, one or more PT/ILC Representatives who organise testing, and a statistical Expert who helps to statistically analyse the data provided by clients, up to their presentation in the final reports sent to the individual clients.

All Politecnico di Milano personnel must respect the "Code of Ethics", a mandatory document issued by Rector's Decree - Index no. 2852 Prot. no. 53516 of 31 March 2021 (www.normativa.polimi.it), which requires all employees to comply with the indicated values and



rules. This document is correlated with the current National Labour Agreement. The Director General is responsible for the legitimacy, impartiality, transparency and proper performance of the University's administrative activities.

The employment relationship is regulated by Italian Presidential Decree 10.01.1957, no. 3 "Consolidated Law of provisions on the Statute of civil servants of the State and rules for its execution" published in the Official Journal of 25.01.1957, no. 22 as amended, as well as the "Code of conduct of public administration employees" (Presidential Decree 16 April 2013, no. 62 - Regulation containing the code of conduct for public employees, in accordance with Article 54 of Legislative Decree 30 March 2001, no. 165).

Personnel who are not employees yet perform activities that may have an effect on the service provided (scholarship holders, research fellows) sign their acceptance of a declaration of integrity, independence of judgment and confidentiality in compliance with Ministerial Decree 28 November 2000 Official Journal no. 84 of 10.04.2001.

The remuneration of personnel is defined by the National Labour Contract under decentralised bargaining.

All personnel are also required to guarantee the confidentiality of the information obtained through their activities as part of the Quality Management System, including information originating from clients. For these purposes, access to the areas of the structures is permitted only for persons authorised by the Structure Manager.

The managers undertake not to involve structures in activities in which they do not have adequate expertise and which may reduce their reliability in terms of impartiality and integrity of judgment. The Politecnico does not provide remuneration based on the number of tests/calibrations performed or based on the result of such tests/calibrations.

To guarantee the impartiality and independence of the laboratories for the tests/calibrations carried out, personnel who perform the activity are not directly employed by sectors that commission the activities for internal clients.

Each structure is responsible for identifying the risks of impartiality, establishing the methods for their assessment in terms of their impact on the activities performed and the validity of the test and calibration results so as to be able to demonstrate how those risks are eliminated, minimised and/or controlled. This analysis also involves a set of rules to guarantee that the impartiality risks are continuously monitored and re-examined.

## 4.2. Confidentiality

All Politecnico di Milano personnel must respect the "Code of Ethics", a mandatory document issued by Rector's Decree - Index no. 2852 Prot. no. 53516 of 31 March 2021 (<a href="www.normativa.polimi.it">www.normativa.polimi.it</a>), which requires all employees to comply with the indicated values and rules. This document is correlated with the current National Labour Agreement. The Director General is responsible for the legitimacy, impartiality, transparency and proper performance of the University's administrative activities.

With regard to ISO/IEC 17025 accredited laboratories, if there is information that the laboratory must make publicly available (by virtue of Laws/Decrees or the activities performed), each Structure Manager will identify the most suitable information to be used to communicate such aspects to the client and will indicate the contents of the information and to whom it will be provided (unless this is not permitted by law).

All documentation relating to other activities performed by Politecnico structures, is treated confidentially and sent only to the recipients, guaranteeing correct levels of control and controlled disclosure based on specifications and directives applicable to the individual cases.



Information about the client obtained from sources other than the client, is considered private and shall not be disclosed to other entities that are not involved in the activities carried out for that specific client by the laboratory.

All personnel who operate for any reason on behalf of the Politecnico laboratories must respect the requirements of impartiality and confidentiality expressed in this manual and in the applicable contractual documentation.

An Ethics Committee has been established at Politecnico di Milano. The Committee has the duty to provide opinions and assessments to the structures directly involved and to the Politecnico di Milano governing bodies to guarantee that activities are performed in accordance with the ethical principles defined by international and national legislation and the internal Code of Ethics. The Ethics Committee is responsible for monitoring and updating mandatory documents relating to the conduct, impartiality and confidentiality that all personnel, permanent and temporary, are required to respect when signing the contract.

#### 5. STRUCTURAL REQUIREMENTS

The Politecnico is an autonomous public university of the Italian Republic which operates in the interest of society and in respect for human dignity, ensuring freedom of research and teaching as guaranteed by the Italian Constitution.

The Politecnico adopts a network-based territorial model, split into Schools, Departments, Campuses and Central Administration.

Schools are recognised as autonomous cultural and educational projects divided into study programmes. The proposal for their establishment is made by a group of professors and is subject to the opinion of the Programme Boards which will make up the school, if already active, and the constituent departments. The establishment of the School is considered by the Board of Governors, which approves the project subject to the opinion of the Academic Senate. The programmes that constitute the school may be composed of one or more levels and active on one or more campuses. If a programme is based on collaboration between several schools, the Academic Senate identifies the school of reference solely for administrative functions.

Departments are the University structures in which human resources are enhanced and coordinated for research and teaching activities. They are responsible for research activities in sectors that are coherent with each other based on contents and methods or objectives, as well as the development of expertise for the corresponding educational activities. Departments are established based on an independent scientific and cultural project.

The proposal for their establishment is made by a group of professors. The establishment of a Department is considered by the Board of Governors, which approves the project subject to the opinion of the Academic Senate.

Departments have organisational and managerial autonomy within the limits fixed by the Statute and by existing legislation.

Departments carry out research and consultation activities based on contracts and agreements, as well as technological transfer, testing and certification activities.

The institutional duties and testing and calibration activities are carried out in the departments and in the laboratories of the Central Administration. Annexes 2, 3 and 4 set out the structures adhering to the Politecnico Quality System (PQS) that have UNI EN ISO 9001 certification, UNI EN ISO/IEC 17025 accreditation and ministerial or regional recognitions.

Campuses are governance structures outside the Province of Milan that are aimed at promoting and supporting the activities carried out therein by the University schools and departments.

Campuses are established based on a long-term development process that integrates teaching and research activities with the relationship with the local area. The proposal for their establishment is



made by the Rector, or one or more departments or schools, and is approved by the Board of Governors subject to the opinion of the academic senate.

The Central Administration is responsible for the administrative, financial and technical management and overall organisation of the University's resources and personnel, as well as the legitimacy, impartiality, transparency and proper performance of the University's administrative activities.

The Director General is the head of the technical-administrative staff, including managers.

The Politecnico is governed by a Rector who acts as its Legal Representative.

In the Annexes, the Quality Manual contains organisation charts of the Quality Assurance Service (ANNEX 1) and the testing laboratories (subsequent ANNEXES). For the detailed, nominal organisation charts of the individual structures, see the structures' internal documents. All documentation regarding the Politecnico's organisational structure is available for consultation on the intranet.

For the particular organisation of the Politecnico and its PQS, the University's Quality Manager is a member of the QAS who also acts as QAM for the LAT Calibration Centre for all product sectors that have not defined a specific local QAM for the accredited calibration activities.

The QAS operates according to an organisation defined by the Head of Service with the Area Head and described in the internal document "QAS Organisation Chart" (QAS /DOC.00.003).

The Politecnico structures organised in conformity with this Quality Manual may be organised autonomously based on their own organisational documents or statutes, and they may adhere to the Politecnico Quality System (PQS).

For University structures, the QAS recognises the correct application of the Quality Management System through adhesion to the PQS according to the methods indicated in the management procedure "Support service for PQS internal adhesion" (QAS/MGP.07.052).

Through the adhesion system, the QAS guarantees that the adhering structure performs the activities falling within the scope of application of the QMS chosen in conformity with the requirements of the PQS, also in circumstances where the scope of application of the adhering structure is not directly or immediately attributable to the scope of application of the PQS. Therefore, for the scope of applying the PQS regarding the multidisciplinary experimental activities of testing, calibration (Accredia and otherwise) and consultation for the design of quality systems, non-institutional training activities and special projects for university teaching via the internal adhesion system (and therefore via QAS control over internal structures), the Testing Lab for Materials, Buildings and Civil Structures (LPMSC) and Thermometric Research Laboratory (MRT) at the Energy Department, have adhered to the PQS. They have adopted its rules in order to obtain, respectively, the status of notified body in relation to the CE marking of construction products and laboratory testing for System 3 certification in conformity with harmonised standard EN 442-1 for requirements 3, 4, 6".

In particular, Regulation (EU) no. 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC and Ministerial Decree 156/2003, insofar as it is not in contrast, regulate the criteria and notification methods of certification, inspection and testing bodies in the sector of construction products. For the purposes of the authorisation, the aforementioned Ministerial Decree states that "the body adopts a structure and procedures compliant with the standards of the UNI CEI EN 45000 series (replaced by the 17000 series) pertinent to the type of authorisation requested" (Art. 10). To this end, the body must establish a Quality Manual and the documentation envisaged by Art. 10 of the decree in question, to be attached to the authorisation request. In compliance with the aforementioned Ministerial Decree, the LPMSC has implemented a Quality Management System by adhering to the Politecnico Quality System and obtaining



adhesion to the PQS, whose maintenance is also guaranteed through audits carried out by the QAS. Furthermore, the Head of Quality Service, jointly with the President of the Certification Committee of the LPMSC, approves the management procedure of the LPMSC which regulates the "Assessment and verification of the constancy of performance of construction products". Finally, the QAS is a permanent member of the Certification Committee. If not otherwise defined, its representative is the Head of Service (or his/her delegate).

The activities carried out in conformity with the accreditation and/or certification standards apply to the structures that have adhered to the University's Quality System according to the methods envisaged by this Quality Manual, and include, based on the specific scope of application:

- updates and consolidation of internal know-how;
- acquisition of orders and contracts;
- procurement;
- consultation for third parties;
- training internal and external to the Politecnico;
- design, management and coordination of training activities;
- management of procedures to establish and activate Master's degrees;
- teaching support;
- orientation;
- execution of tests and calibrations;
- calibration and maintenance of testing instruments and equipment;
- assessment, qualification and training of personnel.

Laboratory activities are carried out in such a way as to guarantee conformity with the relevant standards and with particular regard to ISO/IEC 17025. The management, which is responsible overall for technical activities, obtaining the resources necessary to guarantee the required quality in the laboratory operations and guaranteeing that ACCREDIA requirements are satisfied, consists of the Department Head and Department Manager. The Laboratory Manager acts autonomously in the operational management of the activities performed. In the event of conflicts or specific requirements for resources, the Laboratory Manager may contact the Department Council, which has decision-making power over the department management.

The technical direction of the Testing Lab for Materials, Buildings and Civil Structures, which establishes the strategies and business lines of the laboratory, is entrusted to the Scientific Committee, chaired by the laboratory Scientific Director.

The technical direction of the LPMSC is supported by a Management-Administration, that is, resource management (economic, personnel and instrumental), entrusted by the Politecnico di Milano Head of Research Support Services to the Head of Service.

The responsibilities, authority, internal relations, expertise and duties of the personnel in structures adhering to the PQS are defined in documents controlled within the structures and sent to the QAS.

#### The Rector:

- legally represents the University, provides guidance, initiatives and coordination of scientific and teaching activities, and is responsible for pursuing the University mission according to quality criteria and in respect for the principles of effectiveness, efficiency, transparency and merit. In particular, he/she:
  - o presents the University's multiyear strategic planning document to the Board of Governors, considering proposals from and opinions of the Academic Senate;
  - o presents the annual and three-year budget and final account to the Board of Governors, considering proposals from and opinions of the Academic Senate;
  - o presents the Director General to the Board of Governors, considering proposals from and opinions of the Academic Senate;



- designates external members of the Board of Governors based on profiles of expertise defined by the Academic Senate;
- o takes the initiative in disciplinary proceedings relating to professors;
- o issues University regulations via decree;
- o convenes and chairs the Academic Senate, coordinating its activities;
- o convenes and chairs the Board of Governors, coordinating its activities;
- o convenes and chairs any joint meetings of the Academic Senate and Board of Governors, coordinating their activities;
- o calls the University Conference;
- o ensures respect for the Statute and regulations concerning the university system.
- exercises any other function expected from existing legislation, this Statute, or University regulations which is not expressly attributed to other bodies;
- appoints an Executive Vice Rector from among full professors to replace him/her in all functions in the event of impediment, absence or early termination, until the newly elected rector is invested;
- appoints from among the professors:
  - o a Vice Rector of the University;
  - o a Campus Vice Rector for each campus.
- may task professors with conducting various institutional duties, informing the Board of Governors and the Academic Senate of this;
- signs approval of the University Quality Manual or appoints a delegate to do so.

To facilitate implementation of University policies, the Rector may delegate specific functions to tenured professors, informing the Board of Governors and the Academic Senate of this. Delegations are granted via Rector's Decree (Statute – Art. II.2, Sections 1 and 7). In relation to activities managed through the Quality Management System, the Rector works with the Director General to name a delegate for quality assurance who is responsible for resolving problems and managing quality initiatives that involve the University as a whole. Within the limits of the duties assigned, this delegate has the authority and independence to guarantee the management of the Politecnico Quality System in conformity with the strategic decisions defined by the governing bodies and the Rector's Quality Policy declaration. The Director General verifies the University Quality Manual as part of the PQS and approves it.

#### The Academic Senate:

- guides the University's scientific and teaching activities, proposing solutions for the optimal management of resources;
- develops proposals and mandatory opinions with regard to:
- the three-year development plan;
- the University's annual and multiyear provisional budgets;
- the University's final budget balances;
- the establishment, modification and closure of schools, departments and campuses and the respective establishment projects;
- the establishment, modification and elimination of study programmes;
- the coordination and liaison between departments and schools, including the academic calendar and the planning and regulation of access to study programmes;
- the establishment of other coordination or service structures for research and teaching;
- the Director General proposed by the Rector.
- The Academic Senate approves:
- requests for professors to join departments or study programmes in the event of differing opinions among the bodies in charge;



- the general University Regulations;
- new teaching structures and changes to existing structures;
- the regulations, including those under the remit of the departments, schools and campuses related to teaching and research and the Code of Ethics, subject to the favourable opinion of the Board of Governors;
- the establishment of PhD programmes, Masters and specialisation schools.
- It identifies the competence profiles that characterise external members of the Board of Governors:
- Through a resolution adopted by at least a two-thirds majority of members, it may present the electoral body with a motion of no-confidence in the Rector, after at least two years have elapsed from the start of the Rector's mandate, and at least one year from the previous motion;
- At the Rector's request, it decides on violations of the Code of Ethics that do not fall under the remit of the Disciplinary Board.

#### The Director General:

- is responsible for the administrative, financial and technical management and overall organisation of the University's resources and personnel, as well as the legitimacy, impartiality, transparency and proper performance of the University's administrative activities:
- coordinates the Heads' activities to achieve the objectives indicated by the bodies responsible in the Political Administration according to the criteria of efficiency, effectiveness and affordability;
- carries out the general guidance, management, coordination and control of University personnel and exercises disciplinary power;
- directs the implementation of programmes defined by the governing bodies, even based on specific projects, and fulfils the necessary acts of management;
- presents the Academic Senate and Board of Governors with an annual report on the activities performed and the results regarding the objectives defined by the governing bodies:
- prepares the provisional budget, the final account and the respective technical reports based on financial planning and the allocation of resources, even on a multiyear basis;
- may delegate the conduct of specific functions to managers working at the University;
- has autonomous powers of expenditure within the limits of budget allocations;
- may appoint a deputy from the managers at the Politecnico to replace him/her in all functions in the event of impediment, absence or early termination, until the new Director is invested:
- acts as a reference for problems and quality management initiatives involving the University;
- guarantees management of the Politecnico Quality System in conformity with the strategic decisions defined by the University Bodies and the Management Policy to guarantee the quality defined by the Rector;
- replaces the Rector in approving the University Quality Manual;
- represents the Politecnico di Milano when interacting with public or private accreditation and certification bodies;
- guarantees implementation of the Quality Policy expressed by the Rector;
- guarantees the availability of resources to implement and maintain the PQS;



- ensures that the Quality Management System and its implementation are compliant with the University's general objectives;
- verifies and signs the University Quality Manual.

The Director General coordinates the activities of the Heads and equivalent roles, ensuring their activities conform to the objectives and programmes of the University governing bodies, and ensuring respect for the related directives.

The Directors coordinate the operation of the offices and services of the University. They are responsible for financial, technical and administrative management, including acts that bind the Administration externally by way of autonomous powers of expenditure and the organisation of human, instrumental and control resources. They are exclusively responsible for administrative activities, management and the respective results.

The Head of Infrastructures, Estates and General Services, which is split into six services including the QAS, receives reports from the service managers (responsible for the organisational units) who work with the Head to achieve the objectives indicated by the Political Administration based on criteria of efficiency, efficacy and cost-effectiveness for the optimal allocation of available resources pursuant to existing legislation.

The Director General coordinates the activities of the Department Managers and is responsible, together with the Department Head, for management of the Department.

#### The Department Manager:

- is responsible for the financial and administrative management of the Department together with the Director General and Department Head as defined in the University Regulations and Statute.
- implements and coordinates administrative-accounting activities based on the directives assigned for his/her competencies by the Director General and by the Department Head.
- is responsible for evaluating the Technical/Administrative Staff of the structure, based also on the opinions of the respective internal users and Department Head;
- has the duty to report to the Director General and to the Department Head all cases in which the procedures adopted by the University do not allow the departmental objectives to be reached or where they appear inefficient or ineffective;
- acts as secretary, taking minutes at Department Board meetings.

#### The Area Head:

- is responsible for the financial, technical and administrative management of the Area under his/her remit by way of autonomous powers of expenditure and the organisation of human, instrumental and control resources;
- directs the implementation of projects and management (resources, functions) assigned to him/her;
- signs approval of all documents, with administrative validity and external commitment.

#### The Head of Service:

- acts in conformity with the directives of the Head to whom he/she reports;
- manages, coordinates and controls the activities of his/her service;
- manages personnel and financial and instrumental resources assigned to his/her;
- signs approval of all system documents with organisational validity;
- directs implementation of projects relating to his/her service.

The assignment of additional or different functions falls under the remit of the Area Head. The assignment as Head of Service lasts one year, effective from the date the interested parties were notified of the relevant decision. This period may be further extended, subject to assessment of the



activities performed in accordance with existing legislation. The Head of Service represents management within the service itself and acts in conformity with the directives of the Head to which he/she reports.

The Quality Assurance Service (QAS) is responsible for the operational management of the PQS. *The University Quality Assurance Manager:* 

- guarantees the implementation and monitoring of the Politecnico Quality System;
- drafts and supervises the controlled distribution of the Quality Manual and the Management Review;
- ensures the performance of internal and external audits;
- promotes the maintenance of relationships with accreditation and certification bodies, particularly Accredia and Italcert;
- promotes activities aimed at spreading/promoting the culture of Quality;
- signs approval of the general documents of the quality system without organisational validity;
- supervises the activity of the LAT Centre and the LAB.

#### The Local Quality Assurance Manager:

- guarantees the performance of monitoring the Politecnico Quality System locally in agreement with the University's Quality Assurance Manager and the staff of the Quality Assurance Service:
- collects and supervises management review(s) from the local structure of reference;
- collects and organises aspects of the Quality Management System for the local structure.
- promotes activities aimed at spreading/promting the culture of Quality locally in agreement with the Quality Assurance Service.

#### The Manager of Calibration Centre LAT no. 104:

- coordinates, monitors and controls activities relating to the Centre itself, guaranteeing resources, skills and conformity with the rules of reference for the activities carried out by the Metrology Centres and with the requirements of Accredia DT;
- signs approval of the calibration certificates prepared by the Accredia Metrology Sectors;
- is the Metrology Manager for the Metrology Sectors
- is responsible for relationships with Accredia for the calibration department;
- as Metrology Manager, signs approval of calibration reports for the non-Accredia Metrology Sectors;
- supervises the preparation of operating procedures and signs their approval.

#### The Deputy Sector Manager of Calibration Centre LAT no. 104:

- coordinates, monitors and controls the activities relating to his/her metrology sector, guaranteeing resources, skills and conformity with the rules of reference for the activities carried out and with the requirements of Accredia DT;
- for specific quantities, the position of Technical Director may be held directly by the Manager of the LAT Centre no. 104 thus signing the Accredia calibration certificates prepared by the Metrology Sector;
- serves as contact person and Metrology Manager for the individual sector;
- signs calibration reports for the non-Accredia Metrology Sector;
- supervises the preparation of operating procedures and signs their approval.



## The Representative for LAB no. 1275 Laboratory:

- guarantees application of the 17025 standard and Accredia requirements for all sites of the multi-site laboratory;
- supervises and monitors the University QMS in collaboration with the University QAM;
- collects and analyses management reviews from the sites of the multi-site laboratory in collaboration with the University QAM;
- maintains relationships with Accredia.

#### The Department Head:

- is responsible for representing the Department,
- convenes and chairs the Board and Council and executes the respective resolutions.
- promotes department activities, oversees compliance with the laws, Statute and Regulations regarding the department.
- The role, functions, election methods, period of mandate and incompatibilities of the Department Head are defined by the Statute, the University General Regulations and by the Regulation for Administration, Finance and Accounting.
- As established by the Statute, the Head designates a Deputy Head, notifying the Department Board of this.
- he/she represents the Department and interacts with the University's governing bodies. he/she promotes department activities and oversees compliance with current standards, Statute the and University Regulations. In particular, he/she:
- convenes and chairs the Board and Department Council, carrying out their respective resolutions;
- oversees teaching and research activities within the department and verifies professors' fulfilment of the duties established by existing legislation;
- has powers of representation when interacting with third parties and signs agreements and contracts in harmony with the orientations expressed by the Academic Senate and in conformity with the provisions of the Board of Governors according to the procedures established as part of the Regulation for Administration, Finance and Accounting;
- approves acts relating to participation in tenders for granting loans and contributions to research and technological development;
- is responsible, pursuant to the provisions of Art. 17, Section 4, for departmental organisation and management, as well as keeping archives of official records;
- identifies adequate internal departmental organisation aimed at the efficiency and effectiveness of the services in agreement with the Director General and Department Manager and in collaboration with the Department Board;
- makes funding requests for submission to the Board of Governors;
- is the recipient of all real and personal property available to the department, subject to what is expressly specified by the General Regulation and the Regulation for Administration, Finance and Accounting;
- exercises within the Department every other duty stipulated by existing regulations, the Statute and University Regulations and not expressly attributed to other bodies supervising activities at the LAT Centre and LAB;
- is elected by the Department Board from among full professors in the Department employed full-time or those who choose to be so in the case of election, and he/she is appointed by Rector's Decree;
- The mandate of the Head lasts for three years, and can be renewed once;



- The Head designates a Deputy Head, notifying the Department Board of this. The Deputy
  Head, chosen from among full-time full professors and appointed by the Rector, replaces
  the Head in all his/her functions in the event of impediment, absence or early termination
  until the newly-elected Head is invested. The Head may delegate specific duties to other
  professors or personnel representatives;
- appoints the local QAM;
- appoints the Laboratory Manager.
- delegates the Structure Laboratory Manager to sign the test reports

#### The Department Board:

- coordinates research and teaching activities under the remit of the Department in conformity with the general guidelines expressed by the University governing bodies and in line with available resources;
- approves changes to the project establishing the Department;
- activates call procedures for full and associate professors based on the allocated resources and adopts calls for researchers, first acquiring the opinion of the Schools where the institutional teaching duties are to be fulfilled;
- presents proposals for calls for professors to the Board of Governors;
- works with Schools to agree on the coverage of activities in the institutional training programmes, guaranteeing equitable division of teaching duties among professors in the Department;
- presents proposals to the Academic Senate for the establishment of PhD programmes, firstand second-level Masters and specialisation schools consistent with the department project, even in agreement with other departments;
- presents proposals to the Academic Senate for structures to coordinate research activities in specific areas, with recourse to adequate organisational methods that involve several departments;
- coordinates initiatives of scientific interest, even in collaboration with external entities, and submits the related proposals to the University governing bodies;
- considers the establishment of research, consultation and teaching contracts and agreements;
- outlines the general criteria for the coordinated use of resources allocated to the Department;
- provides advanced approval to use funds for costs that must be authorised by the Board of Governors pursuant to the Regulation on Administration, Finance and Accounting;
- regulates access to the Department, individual laboratories, workshops and other departmental services, also for the purposes of security;
- adopts the Department Regulation at the initiative of the Head.

#### The Department Council:

• has the duty to assist the Head and Board in managing the Department and carries out preliminary activities. If provided for by the Regulation, the Department Board may entrust the Council with decision-making duties, including those set out in Art. 22, Section 7, excluding letters a), b), c) and l) of the University Statute.

The Structure Laboratory Manager (Department or Central Administration):

- supervises and coordinates laboratory activities;
- issues directives for research and planning development of the laboratory;
- signs test reports for approval when not otherwise established.



The Scientific Director of the Testing Lab for Materials, Buildings and Civil Structures (LPMSC):

- implements the strategies and development of the laboratory defined by the Scientific Committee and is responsible for their prompt, correct implementation;
- convenes and chairs the Scientific Committee, drafting its agenda
- submits any proposals for changes to the LPM regulation to the Scientific Committee,
- approves the operating procedures prepared by the competent personnel,
- views expenditure proposals amounting to less than €10,000 submitted by Unit Managers or their delegates.

The Unit Manager of the Testing Lab for Materials, Buildings and Civil Structures (LPMSC):

- is responsible for Unit operations in terms of:
- design, assembly and execution of tests;
- management of equipment (calibration and maintenance);
- management of systems (functionality and maintenance);
- management of spaces under the remit of the unit and access to those spaces;
- respect for workplace safety rules.
- The duties of the Head of Service may be delegated in whole or in part to the Unit Managers (and/or to the competent Technical Managers).

The Delegates of the Head of Service (DHS) assume the duties of the Head of Service for sectors (macro-units) or duties under their remit. The Testing Technical Manager or Laboratory Technical Manager (LTM):

- collaborates with the Manager to establish and perform laboratory activities;
- plans testing activities;
- signs test reports for verification.

In the specific case of the LPMSC, the Technical Manager is a technician with experience in carrying out mechanical, physical and chemical tests and is capable of using the experimental equipment in the relevant Unit.

Under the coordination of the Head of Service and/or Unit Manager, he/she:

- manages the test samples;
- performs experimental tests;
- drafts test certificates/reports.

Testing Technician or Technical Operator:

- collaborates with the Testing Technical Manager or Sector Manager to plan the testing and calibration activities;
- completes the necessary technical records;
- performs testing or calibration activities in conformity with the specifications and standards in force.

With regard to presence throughout the area, Territorial Campuses with the following structure are established:

*The Campus Vice Rector, appointed by the Rector:* 

- convenes and chairs the Board of Reference and executes the respective resolutions;
- submits the Campus Development Plan and Campus Regulation to the Academic Senate for approval;
- carries out all other assignments delegated by the Rector.



The Board of Reference, the guidance, planning and management body of the Campus:

- defines the Development Plan to be submitted to the Board of Governors for approval, subject to the opinion of the Academic Senate;
- develops requests for financial resources, spaces and personnel;
- distributes the financial resources allocated to the Campus in coherence with the Development Plan;
- directs student orientations and the promotion, logistics and management of programmes active on the campus in agreement with the schools;
- works with Departments to facilitate and strengthen research activities;
- promotes and develops technological transfer activities, also in collaboration with local entities and producers.

The Board of Reference is composed of:

- Campus Vice Rector, who acts as chair;
- Department Heads or their delegates involved in Campus activities;
- the Chairman or delegates of the Study Programme Boards active on the Campus;
- a number of elected student representatives equal to the minimum required by the legislation in force;
- a personnel representative designated by the Campus Vice Rector;
- representatives of the local community appointed by the Rector.

#### The Technical Expert:

is an individual (University professor or external person) who provides consultation for laboratories based on his/her expertise and/or uses laboratory resources to carry out experimental activities.

Technical Experts also operate within the laboratory with the following purposes:

- technical/scientific support in the performance or design of testing activities or complex operations;
- development of new equipment and innovative testing methods.

Technical Experts must be trained in the standards of reference for the Quality Management System, except where his/her intervention is exclusively technical/scientific.

#### The PT/ILC Representative:

- manages enrolment and contact with participants in a certain testing method;
- works with the Coordinator to manage instructions for shipping samples;
- checks incoming samples and the attached documentation;
- prepares samples for shipping to the calibration centre that will perform the test;
- manages the samples at the end of the test, including their return to the participants;
- completes forms relating to the proficiency test and ensures they are archived.

## The Method Coordinator:

- establishes the proficiency testing method following the specific form (LMR/FOR.21.002 "Complete Testing Method") and the provisions in Section 4.4 of standard UNI CEI EN ISO/IEC 17043:2010;
- is responsible for the proficiency testing method in all its parts;
- identifies the tests to be subcontracted and selects the laboratories able to perform them;
- establishes the proficiency testing budget with the Laboratory Manager;
- is responsible for jobs and procurements of the testing method, although approval falls under the remit of the Laboratory Manager;
- selects collaborators within the group of ILC/PT representatives to manage the test;



- chooses the method of encoding the participants and sample sets and is the only person aware of them:
- oversees the impartiality and confidentiality of the data;
- develops the statistical plan for the testing method, relying on collaboration with the Statistical Expert;
- performs statistical analysis of the testing method;
- drafts the report and signs its approval together with the Laboratory Manager.

#### The Statistical Expert:

- collaborates with the test coordinator to establish the statistical plan of proficiency tests pursuant to point 4.4.4 of standard UNI CEI EN ISO/IEC 17043:2010;
- may collaborate with the coordinator in drafting calculation sheets for statistical analysis or suggesting dedicated software for the necessary analyses.

The functioning of the Quality Management System is guaranteed by the QAS and by the various duties of the departments identified for such activities, as defined above.

The QAS has the duty to update the documents describing the Politecnico Quality System when necessary and in collaboration with the QAMs of the internal structures involved, guaranteeing their conformity with the standard of reference in order to meet customer requirements and any mandatory requirements.

The QAS periodically convenes meetings with the various QAMs and sets the dates for the various phases of the "Management Review" in order to verify the adequacy of the Quality System. At these meetings, the QAS and QAMs examine the implementation of the Quality System and the effectiveness of improvement activities.

For testing and calibration activities, the Laboratory Manager, in collaboration with the QAM, works to prevent, remove and/or resolve activities affecting the quality of the tests/calibrations and the service provided to clients. For the structures of Central Administration, the Department Head or Laboratory Manager has the authority to impose the shutdown of critical activities if serious conditions exist which unfavourably affect the quality of the tests, calibrations and/or service.

The continuity and maintenance of the Politecnico Quality System are guaranteed even in the case of organisational changes through the procedures "Politecnico Quality System Management" and "Personnel Management" (QAS/MGP.08.051 and QAS/MGP.12.001). Furthermore, to guarantee the continuity of testing and calibration activities, suitable systems are in place to substitute key figures in the laboratories. In general, for example, the following rules apply:

- the Laboratory Manager is replaced by the Department Head,
- the QAM Laboratory Quality Manager replaced by the University Quality Manager.

The technicians in charge of testing and calibration are interchangeable in accordance with their respective professional profiles and authorisations. If particular authorisations or licences are required (e.g. for non-destructive testing) in the absence of a technician with the necessary requirements, the testing activity is suspended or delayed.

The technicians in charge of testing and calibration are coordinated by the respective Testing Technical Manager and have the necessary expertise to perform their tasks. The Testing Technical Managers are coordinated by the Laboratory Manager and the Laboratory Managers are, in turn, coordinated by the Department Head. The Department Head grants autonomy to the various levels, each for their own skills and authorities, in carrying out their duties, and provides constant professional development and all resources (human and instrumental) necessary to perform the tests.



*University Information Systems (ASICT)* 

Guarantees the development and management of an integrated system of applications and services that use ICT technologies to best support the needs and strategies of the University, guaranteeing respect for regulatory provisions (e.g. Digital Administration Code, GDPR, ICT Security Measures of the PA, etc.).

Provides an adequate level of service for calculation and storage resources and the infrastructure necessary for the operation of:

- the University's information system;
- systems entrusted to ASICT for hosting by other University structures or partner entities.

Defines and implements the Business Continuity and Disaster Recovery Plan of the University ICE Services in accordance with existing legislation.

Guarantees a level of IT security consistent with regulatory provisions and adapted to University requirements, periodically analysing IT risks and implementation of the necessary technical and organisational countermeasures.

Serves as a reference for assessing the impact on information systems and the respective supporting infrastructures and provision of services, and on the use of ICT technologies in general and projects promoted by the Central Administration or other stakeholders (internal or external to the University).

#### 5.1. Suspension - self-suspension in the LAT Calibration Centre no.104

In implementation of Accredia RG 13, the motivation for the suspension/self-suspension of a sector relating to the LAT Centre no. 104 are indicated below:

- failure to return the Accreditation Agreement signed for acceptance;
- failure to apply the requirements indicated in the signed Accreditation Agreement;
- violation of the requirements of accreditation rules/requirements of the present Regulation;
- negative outcome of assessments in the field;
- unwillingness of the laboratory to undergo unscheduled assessment;
- contractual insolvency;
- failure to resolve findings in accordance with ACCREDIA procedures;
- failure to implement corrections/corrective actions in the case of calibration certificates issued unduly (corrective action may, for example, also lead to the laboratory's decision to withdraw a calibration certificate unduly issued because it falls outside ACCREDIA accreditation or does not comply with the accreditation rules);
- ineffective treatment of unsatisfactory results of participation in PT/ILC;
- failure to manage complaints;
- changes to the legal entity (e.g. change of company name, transfer of accreditation to another holder);
- failure to promptly communicate the loss of the Laboratory Manager to ACCREDIA;
- exceptional temporary lack of significant calibration equipment (excluding unavailability of the instrumentation for planned calibration);
- temporary unavailability of laboratory premises (for example, due to lack of control of environmental conditions);
- transfer of the laboratory.

The suspension procedure involves the laboratory's immediate interruption of calibration certificate issuance. The suspension may be total or partial, thus involving only part of the sectors or accredited quantities.

If the suspension is total, the assessments in the field of planned supervision are also interrupted for as long as the suspension of accreditation continues.



In the event of self-suspension, the laboratory will send the relevant Technical Officer (TO) a written request for self-suspension, specifying the reasons, indicating the presumed duration and attaching DA-00 and DA-05 when necessary.

The TO submits the request for self-suspension to the DDT. The reasons and duration related to the self-suspension request are assessed by the DDT, which may modify and/or supplement the conditions and timescales planned to recover conformity, nevertheless ordering the assessments necessary to check for full conformity at the end of the self-suspension period.

The requesting laboratory is informed in writing about the assessment activities planned for restoring conformity and the maximum period granted, which may not be longer than 12 months within the certificate validity period, at the expiry of which the CSA-DT will consider the consequent actions.

The list of laboratories published on the ACCREDIA website is updated to report the self-suspension of the activity.

The CSA-DT is informed of the self-suspension of accreditation.

The self-suspension of accreditation does not involve forfeiture of contractual obligations with ACCREDIA.

#### 5.1.1 Impartiality and confidentiality of personnel at the LAT Calibration Centre no. 104

Like all personnel (employees and collaborators) of Politecnico di Milano, workers in the LAT Centre no. 104 are also required to respect the "Code of Ethics", a mandatory document issued with Rector's Decree no. 2852 Ref. no. 53516 of 31 March 2021 (<a href="www.normativa.polimi.it">www.normativa.polimi.it</a>) which requires all employees to comply with the indicated values and rules. This document is correlated with the current National Labour Agreement.

In particular, personnel who are not employees yet perform activities that may have an effect on the service provided (scholarship holders, research fellows) sign their acceptance of a declaration of integrity, independence of judgment and confidentiality, in compliance with Ministerial Decree 28 November 2000 Official Journal no. 84 of 10.04.2001.

The Director General is the guarantor for University personnel. The LAT Centre no. 104 Manager guarantees that such indications are respected and above all that the signatures of any personnel who are not employees are present.

The risks associated with the impartiality and confidentiality of personnel are assessed in the Structure Document drafted within the laboratory for each physical quantity subject to accreditation. In order to monitor its personnel who operate in various guises within the University, the Politecnico di Milano has activated an electronic platform known as "Politecnico di Milano Human Resources Portal" to perform all-round management of personnel. Human Resources is responsible for managing and monitoring the skills of all Politenico di Milano employees and has developed its own model known as "performance model". The service periodically updates the personal files of individual employees, including assessments made by the relevant Managers as well as the performance achieved during the year of reference.

## 6. REQUIREMENTS RELATING TO RESOURCES

#### 6.1. General information

The Politecnico testing/calibration laboratories carry out tests and calibrations with standard methods or methods validated by the laboratories or recognised as valid by the accreditation body. If a standard does not contain sufficient information to carry out the analyses, the laboratory prepares specific test or calibration procedures that provide a unique interpretation of the methods to perform such tests, sampling and calibrations.



Those documents indicate the equipment, tools and instruments necessary to perform the calibrations and tests and identify all parameters that may affect the test/calibration (and the respective control and recording methods).

The management of testing and calibration activities as a whole involves the phases to review requests, offers and contracts, the choice of methods, assessment of the necessary skills and any deviations from the contract or modifications thereto once the activity has begun. The aspects indicated above are identified and listed in the following documents:

- Management of calibration activities (QAS/MGP.99.015);
- Management of testing activities (QAS/MGP.07.057);
- Design and development process (QAS/MGP.07.050);
- Management of equipment (QAS/MGP.01.008);
- Estimate of measurement uncertainty as part of testing and calibration experimental activities (QAS/GL.02.012);
- Control of results (QAS/GL.01.011);
- Validation of methods as part of experimental activities (QAS/OPI.07.058);
  - Regulation for services on behalf of third parties of Politecnico di Milano Operating procedures/technical standards.

These documents also define the methods used to verify the validity of the results, and the methods used to inform the client if the laboratory itself decides that the requested testing/calibration methods are inappropriate or obsolete. These documents also specify the records to be kept and the formats to be used, in particular, for:

- Records of sample acceptance;
- Records of sampling outcomes;
- Environmental records of sample storage;
- Calibration certificate/calibration report examples;
- Test report examples;
- Technical reports.

Finally, the presentation of the results provided to the client in services relating to tests, calibrations, research, consultation or anything else faithfully reflects the findings obtained in the operational phases and must satisfy what was agreed upon in the offer phase and formalised in the order or contract, with particular attention to:

- Accuracy, objectivity, intelligibility and confidentiality of the results;
- Completeness, in terms of meeting all client requests, including the necessary terms for any interpretation of the results and an indication of the methods followed.

#### 6.2. Personnel

The Structure Manager guarantees the competence and impartiality of internal and/or external personnel, if present.

Each Structure Manager identifies the necessary duties to conduct the activities and guarantees the documentation, for example, an organisation chart, of the relationships between the positions identified and the position of the Structure within the Politecnico. In particular, the relationships between the various positions must be highlighted, specifying the responsibility, authority and interdependence of all personnel who manage, execute or verify the work and have even a potential influence on the services offered.

Details about the indications regarding the foregoing are contained in the "Personnel" management procedure (QAS/MGP.12.001).



The Politecnico's activities fall under the regulations of the Public Administration and the requirements to access the various roles are defined by these regulations. In particular, the basic documents of reference for positioning personnel are:

- "Personnel" Procedure (QAS/MGP.12.001);
- "Organisation and minimum requirements" procedures or documents pertaining to the individual structures.

The Structure Manager defines annual training/education objectives for personnel by preparing a plan on at least an annual basis. The methods to highlight such planning may vary depending on the structure and complexity of the planned training activities.

The provision of training/education is the responsibility of the structure, which may use the following methods:

- courses established by organisations of proven competence;
- study days;
- national and/or international conferences;
- update/training courses organised internal to the Politecnico;
- job shadowing of expert personnel.

As well as defining the level and type of training required for personnel in the structure ("know-how" or "knowledge"), the Structure Manager will set out the effectiveness verification, being careful to follow the indications explained below.

With regard to "cognitive" training (e.g. use of software, knowledge of relevant standards, etc...) the effectiveness check may be based on a learning test (e.g. end of training test). With regard to more specific training in which a skill/"know-how" is defined (e.g. use of a machine, preparation or execution of a test/calibration, etc...), the effectiveness check will be carried out for the actual skills acquired by the individual (e.g. the trained individual must prove that they know how to use the machine independently, know how to set up the test or execute it, etc...).

When the process is concluded, the recipient of the education/training records its terms in the personal file/curriculum vitae.

In the case of ineffectiveness, the Structure Manager analyses the causes and plans new training. For personnel employed in experimental activities (tests or calibrations) the specific qualification is recorded and objective checks of the training/education are performed and archived by the structure itself.

The structures that decide to adhere to the PQS rely on support from QAS personnel, which is implemented through a combination of training and collaboration/assistance activities in accordance with the provisions of the "Support service for internal adherence to the PQS" management procedure (QAS/MGP.07.052).

In view of the different reasons that determined the design of the training course and the primary need to increase technical-specialist/operational skills, the education/training assessment is conducted by applying flexible methods, using one of the following different assessment tools:

- Compilation of a training assessment questionnaire at the end of each course by participants with evaluation;
- Passing a final test with issuance of an attendance certificate or attainment of an authorisation or qualification (as for non-destructive tests);
- Assessment of effectiveness as part of scheduled periodic audits and through interviews or specific questionnaires or through assessments of objective results (for example, outcome of interlaboratory circuits, duplicate tests, etc.).

The training is recorded in accordance with the methods described in the "Personnel" management procedure (QAS/MGP.12.001). The procedure also requires the following documents to be filed among the personnel records:



• Definition of responsibilities, roles and authorisations through pre-existing documents (regulations, reports, letters of engagement, etc.) or specifically prepared documents. Where present, any formal delegations should also be recorded.

Each Structure Manager defines the necessary requirements to obtain authorisation to follow a method (in full or in phases) and maintain it and to assess the significance of deviations in the activity phase (tests and/or calibrations) in terms of:

- Need for specific training on tests and/or use of the instruments;
- Need for a period of training with job shadowing and supervision by authorised personnel;
- Minimum level of education or equivalence in years of experience if the minimum level is not met;
- Methods adopted to obtain authorisation to operate in the sector/area and to maintain it.

Attaining authorisation to carry out tests and/or calibrations is therefore a combination of analysing personal experience, direct observations of the actions of personnel and the result of objective assessments, for example, from:

- Results of interlaboratory circuits/comparisons;
- Results of execution of duplicate tests;
- Possession of certifications/licences (such as qualifications for non-destructive tests);
- Results of tests, investigations, interviews, questionnaires or assessments following the training provided;
- Assessment of objective parameters tied to the performance of the test and the use of any instruments, such as:
  - accuracy assessment: execution of the test (possibly in parallel with an authorised technician) and verification of any deviation in relation to the reproducibility of the laboratory conditions or method;
  - o repeatability assessment: replications of the measurement on homogeneous sample aliquots and check of repeatability by the technician in relation to the repeatability of the method or laboratory conditions;
  - o Results of analyses and tests on unmarked samples;
  - o Compatibility tests.

In addition to the educational requirements needed to access the position and a passing mark on objective qualification tests, personnel newly inserted in a laboratory must be supported and supervised when conducting their activities (different times may be chosen by the Structure Manager for each individual activity).

The result of the assessment and any consequent actions are formalised in the subsequent Management Review and lead to an update of the personnel file of the interested party.

The qualification is lost if the employee causes serious NC during the test activities or does not pass the qualification tests and the actions taken to requalify him/her are unsuccessful. Qualification is also lost when the employee has been absent or has not carried out tests/measurements for prolonged periods of time (based on the rules defined by each structure in relation to the test or calibration activities performed).

At least once a year, the Structure Manager verifies that the laboratory personnel are authorised to conduct the assigned tests/calibrations and that the procedures established have been respected.

At least once a year, the Structure Manager communicates to personnel the duties, responsibilities and authorities assigned to them.

Together with the procedures cited, this Quality Manual represents methods of personnel management and the respective records. In particular, the activities performed are:

- Definition of requirements of competence;
- Selection of personnel by the Structure Manager;



- Training of personnel based on the "Training Plan";
- Increase of organisational-managerial skills related to the management system
- Updates to the management system;
- Introduction of new operating procedures and/or technical procedures;
- Training/education requirements emerging from risk analyses or deriving from corrective actions;
- Updating of software equipment and/or management or operating software used;
- Requirements deriving from mandatory provisions;
- Requirements arising from analysis of the causes of non-conformities, even deriving from unsatisfactory outcomes of the comparison of results between laboratories;
- Internal training;
- Supervises the activities performed for the whole operational, technical and management part. In general, the supervisor-technician ratio should be 1:5.

All activities described apply to personnel irrespective of their type of contract. The monitoring and training activities described above also apply to personnel not directly employed by the laboratories but who, through their activities, influence (or may influence) laboratory activities and conformity with ISO/IEC 17025 and accreditation requirements.

The Structure Manager also gives authorisation to conduct specific activities such as:

- Development and implementation of test/calibration methods for applications of interest to the laboratory and its clients, including the necessary modifications, updates and validations.
- Analysis of the results and expressions of declarations of conformity or formulation of opinions and interpretations is the responsibility of the Structure Manager.

The presentation of the results, their review and approval is the responsibility of the Structure Managers. The laboratory appoints a deputy for such activities in the case of absence to avoid impeding laboratory operations. This information is available from the individual accredited structures.

#### 6.3. Structures and environmental conditions

The Laboratory Manager ensures that the general conditions of the premises do not constitute an impediment to the planned activity, with attention, according to what is applicable, to:

- lighting conditions;
- air conditioning of the premises (humidity and temperature);
- problems related to vibrations, loads, pressurisation, noise levels, etc. (even induced by nearby processes/activities);
- electromagnetic disturbances (such as introducing a prohibition on using mobile devices in areas used for tests or close to sensitive equipment);
- dust and processing residue.

When a new instrument is inserted in the laboratory, the adequacy of the environmental conditions in relation to the use of the instrument, its operating specifications and the presence of other instruments and interference is also assessed. Particular criticalities are reported in the instrument specifications.

The Structure Manager also assesses the environmental conditions in which the activities are carried out, to guarantee both the quality of the services/tests/calibrations and the working conditions for internal personnel. Work areas are prepared in the offices with adequate space, sufficient lighting and ergonomic workstations; laboratories have suitable passageways and work spaces.

Each structure/department has a local officer in charge of managing the health and safety of workers. These officers are coordinated by the central PPS (Prevention and Protection Service). The



test/calibration activities and sample storage occur in environments with controlled temperature and humidity as regards the requirements of the standards and methods used. The maintenance of suitable, controlled environmental conditions is particularly important for the correct storage and use of primary samples. According to the requirements of the specific activity performed, the climate conditions (temperature and/or humidity and/or pressure) are kept under control.

The equipment used to control the environmental conditions is considered as measuring instruments and therefore subject to metrological confirmation, as indicated in the "Management of equipment" procedure (QAS/MGP.01.008).

If the technical personnel ascertain that the environmental conditions are inadequate or likely to negatively influence the activity and the results, they are responsible for promptly informing the Structure Manager, so that he/she may take the necessary corrective actions.

When required by the method used, the environmental conditions to conduct a testing activity or other activity considered critical for the results, are recorded and communicated to the client in the test report.

The structures required to carry out the tests/calibrations are subject to cleaning and ordinary maintenance to guarantee the regular progress of the test/calibration activities.

The cleaning of premises used as a Laboratory (also based on the different Metrology Sectors) is ensured through a University contract. With regard to the cleaning of work benches and laboratory equipment, the Manager guarantees that specific instructions are available.

The maintenance of the Politecnico infrastructures is guaranteed by AGIS (Infrastructures, Estates and General Services). In terms of infrastructure, the following are considered:

- buildings;
- work spaces;
- offices:
- cleaning services;
- support and communication services.

By way of its dedicated sections, AGIS guarantees the Politecnico the means necessary to perform the various activities and to keep them efficient, dealing with their maintenance and technological update.

Infrastructure maintenance is carried out either by specialised external personnel or internal technicians if personnel with the respective qualification and expertise are available.

Each structure maintains records of the interventions carried out on their systems.

The structures independently manage and retain the related records for the maintenance and technological updating of:

- hardware and software, some department ICT services, etc.;
- handling vehicles;
- various workshop machinery and respective equipment.

In addition, it is the responsibility of the Structure Manager to ensure the physical separation between places in which incompatible activities are performed with a view to avoiding any possible contamination and, if necessary, to stop the activities immediately if conditions likely to compromise the results are identified.

For activities beyond the control of the laboratory, the personnel are responsible for ensuring that the requirements in place for test/calibration activities are respected based on the procedures of reference.

## 6.4. Equipment

With reference to the new UNI EN ISO/IEC 17025:2018, the term "equipment" means everything that is generally required to carry out laboratory activities and which may affect the results. The



laboratories have equipment (including measuring instruments, software, reference samples, reference materials, reference data, reagents and consumable materials or auxiliary apparatus) necessary to carry out the accredited tests and calibrations.

During the periodic management reviews, the need to acquire new equipment is verified.

The equipment is selected to ensure respect for the requirements of the methods and the achievement/maintenance of the established levels of uncertainty.

SW, reference materials and reference data (meaning mainly those used for the SW validation) are identified and listed at the individual structures.

All equipment (measuring instruments, reference samples or auxiliary apparatus) used for tests/calibrations falls under the direct control of the Instrument Manager designated within the sector and is subject to verification and periodic maintenance as described in the "Management of equipment" procedure (QAS/MGP 01.008). Equipment management SW is available for all structures on the University intranet.

If the laboratories use equipment that is not owned (e.g. leased, hired) they ensure that specific documentation is issued, certifying that the equipment is nevertheless subject to their control. The contracts signed will have a term at least equal to the validity of the accreditation of the tests/calibrations for which the equipment is used and the equipment is subject to the same acceptance and acceptability checks as the equipment owned by the laboratory.

The Structure Managers have the duty to prepare and provide the Testing Technicians with specific instructions for use (including handling, transportation, storage where necessary) of the equipment and instruments necessary to guarantee their correct use and maintenance when the books and manuals on use of the equipment are not comprehensive or may lead to error. That documentation is available with the equipment and/or in the area of activity.

All laboratory equipment is verified by the Instrument Manager before being commissioned. Upon receipt of what has been procured, the Instrument Manager carries out the acceptance, verifying the accuracy of what was ordered with the records.

The equipment used by the laboratory is suited to guaranteeing the CMC/uncertainties determined by the laboratory. The characteristics of the equipment to be used are indicated in the calibration/test procedures or the instrument specifications.

Through the calibration programme, the laboratory assesses the instrument calibrations to be performed.

The criteria for the metrological confirmation of instruments are indicated in the calibration procedure/instrument specifications.

Periodic verifications of the state of calibration/maintenance are aimed at guaranteeing the traceability of the measurements made and confirming the measurement uncertainty.

These verifications may be carried out at external centres (Italian or equivalent accredited EA which may even operate directly at the laboratory) or by way of internal calibrations. The criteria for guaranteeing a documented and uninterrupted chain of metrological traceability are described in Section 6.5 below.

Primary samples used exclusively to verify the measuring instruments and instruments used for environmental monitoring of the laboratory are also subject to periodic control of their calibration at accredited centres. For the management and calibration of samples and materials of reference, see Section 6.3 above.

In agreement with the Structure Manager, the Instrument Manager carries out (or has carried out by specialist internal or external personnel under their responsibility) the verification of the calibration and periodic maintenance of the equipment, recording its outcome in the laboratory instrument management database.

All equipment and instruments are assigned to expert personnel and protected (insofar as applicable) to avoid changes to the adjustments and calibrations performed.



For maintenance activities, the activities to be carried out and the respective deadlines are planned (as well as internal/external responsibilities) based on information inferred from the manufacturer, manuals and technicians' experience.

Where external services are used, specific agreements define both the operations to be performed and the registration documents that maintenance personnel are required to issue to the structure. Such documents are uniquely related to the measuring device and are archived as evidence of the activity performed.

The LAT Centre no. 104 sectors may perform internal calibrations only on instruments that do not impact the uncertainty of accreditation, subject to information and consequent approval from Accredia DT, which may also plan a specific audit or any audit in the field.

The instruments carry a label containing:

- the date of execution and expiry of the calibration, as well as maintenance and other metrological confirmation operations required;
- the status of the device, e.g. confirmation for use, out of service, some uncalibrated scales (scope of validity of the calibration), etc.;
- the initials of the Instrument Manager.

At laboratories/calibration sectors, the status of equipment and instruments is identified as follows:

- instrument IN USE: equipment that is used and for which periodic maintenance and calibrations are carried out according to established frequencies (based on the instrument specifications);
- instrument OUT OF SERVICE: equipment that is normally in use but, due to fault or noncalibration status, cannot be used; or equipment used outside the control of authorised personnel. The device is temporarily placed out of service until extraordinary interventions have been implemented that guarantee its metrological confirmation for the purposes of correct use.

If instruments and/or equipment used for test/calibration activities are found to be uncalibrated or not adjusted, the technician in charge of the test/calibration informs the Testing/Calibration Technical Manager and Instrument Manager, who assess and document the validity of the results of the previous tests/calibrations (and also the results already issued), as described in Section 7.10 of this Quality Manual.

Laboratory equipment that has been subjected to overloads (power shortages and/or surges), is defective (dropped or struck), or whose calibration is not compliant with the specifications is removed from use, identified and, if possible, segregated to the dedicated area of the laboratory.

After recording the non-conformity, the Instrument Manager manages the analyses as indicated in Sect. 7.10 of this Quality Manual.

Before being placed into (or returned to) service at the laboratory, each instrument undergoes checks made by the Instrument Manager to guarantee the traceability of the measurements made and confirm the measurement uncertainty.

Interim controls are aimed at verifying the maintenance of the metrological characteristics between calibrations in terms of the measurement uncertainty of a device.

The use of planned interim checks of measuring devices is necessary where any risk of unconscious use under non-conforming conditions may compromise its metrological traceability.

Extraordinary controls are required if the devices have been managed inappropriately, have been used outside the control of the authorised personnel, or have undergone a repair or other type of intervention that may have compromised their metrological characteristics and therefore their traceability.

The control is carried out based on documented procedures and/or instructions and represents a further stage in the metrological confirmation of the device.



If appropriate, the interim checks may not include the entire field of measurement of the verified device.

If such controls generate any doubt about maintaining the metrological requirements necessary to guarantee correct use of the measuring device, the person responsible calibrates the device again.

If the calibration of the instrumentation/samples presents corrections or correction factors, the Instrument Manager manages such factors through any indications stated in the calibration/testing procedures.

The equipment (insofar as technically possible) is protected from adjustments that may invalidate the test results.

If the instruments, samples or equipment needs to be sent to external centres for calibration and/or maintenance, the Instrument Manager involved defines the suitable methods to guarantee the integrity of the instruments during transportation and storage at the external centres (and records their movements in an entry and exit record).

The Instrument Managers define the methods to be adopted to correctly transport the instruments to be used during sampling or the performance of tests in the field and the methods for controlling the integrity of the equipment before use on site.

The Instrument Managers also establish the environmental conditions and conditions of use necessary to ensure the proper functioning and storage of the equipment, both for activities at the site and in the field.

All instruments/equipment are recorded in the equipment management software provided to all internal structures. The software allows all records required in this procedure to be made and also allows all necessary reports for the correct management of the set of instruments to be printed out. The Instrument Manager must ensure that:

- a record sheet containing the details of the measuring device and the interventions performed is prepared and updated;
- the status of the measuring device is clearly identified, with particular attention to any out-of-service statuses;
- a schedule of operations to be performed on the measuring devices is kept up to date.

All equipment and instruments are uniquely identified by the Instrument Manager and their records are placed in the specific instruments list. The equipment sheet may be on paper or contained in the instrument management software.

Each equipment sheet must contain at least:

- the identification of the equipment and the respective software;
- possible indication of the firmware version in use;
- possible indication of the software version in use;
- date of commissioning;
- name of manufacturer;
- identification of the model or type;
- serial number or other unique identification;
- calibration and maintenance interventions and metrological confirmation planned for the device;
- location, where appropriate;
- manufacturer's instructions, if available, or references to their location;
- record of all interventions performed on the instrument;
- name of the Instrument Manager.

The Instrument Manager updates or ensures (under his/her responsibility) that other people update the records relating to the instruments for which correction factors emerged after the calibration activities. In this case, the methods for re-checking the correction factors and their application



(record the results read and corrected, automatic correction by the software, etc.) are also documented.

The reference materials are used by the laboratories to conduct the methods entailed. These materials are acquired certified by the manufacturer and verified in the acceptance phase in relation to their integrity and conformity. Before using the reference materials, the technicians check their expiry to avoid their incorrect use (expiry dates are defined upon acceptance for open packaging and for closed packaging and the storage methods).

All reference materials are managed through specific record sheets that uniquely identify the materials, define their expiries (with packaging open and closed), the quantities stored and for reorder, the check of conditions upon receipt, the storage conditions and location, the necessary quality characteristics, etc. Such management extends to all consumable materials in the laboratories, including reagents, kits, solvents, etc.

Where possible, the reference materials refer to SI units. The reference materials prepared within the laboratory are prepared and controlled in accordance with specific procedures.

The reference materials are stored in suitable conditions to guarantee their conservation and inalterability, in specific cupboards, safety boxes, refrigerators, etc.

## 6.5. Metrological Traceability

The laboratories calibrate the instruments (including primary samples used for calibration checks) before they are commissioned and periodically based on the frequencies established by the Instrument Manager. Such checks are based on the laboratory requirements, the type of tests/calibrations performed and the frequency with which the instruments are used.

For calibration services commissioned from external centres, organisations are used that are able to guarantee traceability to the SI, or metrological institutions or calibration centres accredited through the ACCREDIA mark or EA European equivalent. External calibration centres are chosen based on their metrology capacities and their declared calibration uncertainty (such preventive checks are the responsibility of the person requesting the calibration).

If the structure relies on the QAS, reference is made to the "Management of calibration activity" procedure (QAS/MGP.99.015).

Upon each calibration, the Instrument Manager carries out the metrological confirmation.

If the calibration is carried out within the structure, the following must be guaranteed:

- calibrated primary samples or certified reference materials are available;
- the operations are performed based on documented, validated and available procedures for the instructed personnel;
- the environmental conditions are under control;
- the instructed personnel are qualified and skilled;
- the results are adequately recorded.

When the environmental conditions differ from the conditions required by the procedures, the calibration may nevertheless be carried out, applying appropriate corrective factors.

Except in cases authorised by ACCREDIA, it is not permitted to carry out calibration interventions using reference samples held by the Metrology Sectors, as they are dedicated exclusively to calibrating work samples.

The Instrument Manager periodically verifies the adequacy of the deadlines relating to calibrations and maintenance and updates them where necessary.

To guarantee that the measurements refer to the international measuring system, the contents of ILAC P10 are applied and the following are therefore used, based on the assessment made by the Instrument Manager:



- 1. National Metrological Institutes and Designated Institutes (NMI) whose services are suitable and covered by the CIPM MRA agreement within the limits of the metrological capacities (CMC) accepted internationally and published in the KCDB by the BIPM. The CIPM MRA mark shows this affiliation but its use is not mandatory; therefore, when it is absent, the laboratory must check the CMC on the BIPM website.
- 2. Accredited calibration laboratories whose services are suitable and whose accreditation is issued by Accreditation Bodies (ABs) that are signatories to the EA-MLA or ILAC-MRA agreement for calibration purposes within the context and limits envisaged by the CMC published by the ABs.

The use of calibration certificates issued in these two situations is to be considered equally valid, subject to the different value of calibration uncertainty, which must be suited to the requirements of the laboratory. If metrological traceability cannot be obtained from either of the two cases indicated above, the following alternatives are acceptable, provided that appropriate evidence on the competence of the provider is available and in particular, on the traceability and measurement uncertainty of the calibrations supplied:

- 3a NMI whose services are suitable but not covered by the CIPM-MRA agreement. This case should not be chosen based on purely economic or logistical reasons, but should be considered as a last resort when cases 1 and 2 are not available.
- 3b Calibration laboratories whose services are suitable, but not covered by ILAC agreements or by regional agreements recognised by ILAC. This option must only be chosen if providers of type 1, 2 and 3a are not available.

Where possible, the reference materials refer to SI units. To guarantee metrological traceability, certified values of certified reference materials are used, provided by competent manufactures with declared metrological traceability to the SI (using, for example, ISO 17034 accredited manufacturers). It is also possible to directly create SI units guaranteed by direct or indirect comparison with national or international samples (using, for example, the "SI brochure" as a guideline).

When, on the other hand, it is not technically possible to guarantee metrological traceability to SI units, the laboratory will demonstrate its metrological traceability to an appropriate reference, for example, by way of:

- certified values of certified reference materials supplied by a competent manufacturer;
- results obtained with measuring procedures of reference, with specific methods or standards based on consent which are clearly described and accepted as suited to providing measurement results adequate for the use and guaranteed by suitable comparisons.

Reference materials prepared within the laboratory are prepared and controlled as envisaged by the specific procedures and guarantee metrological traceability through one of the systems described above.

### 6.6. Externally supplied products and services

The Structure Manager identifies the requirement (directly or by way of personnel at the structure) and requests the quote. Procurement methods (purchase or tender) follow the requirements established by the RAFC and related legislation in force. The purpose is to guarantee that what is purchased is adequate and compliant with the identified and specified requirements, keeping in mind that the type and extent of controls made are proportionate to the nature and criticality of the good/service purchased, namely its possible influence on the quality of the product/service supplied. Further details of the above can be found in the "Procurement Management" procedure (QAS/MGP.01.006).



The method therefore applies to critical purchases relating to activities falling within the scope of application of the PQS.

Critical purchases generally consist of:

- measuring, testing and calibration equipment and accessories;
- reference samples/materials;
- testing or calibration services and equipment maintenance;
- consumable materials relating to tests and/or calibrations that affect their quality;
- performance of professors and tutoring provided by personnel external to the Politecnico;
- orientation experts;
- performance of technical and scientific support;
- staff training courses;
- infrastructure, i.e. spaces (e.g. classrooms, computerised or not), equipment (even teaching-related), devices, if not belonging to the Politecnico, support services (e.g. publishing, printing, catering, etc.), plant engineering;
- software for experimental activities or calibration.

In the entirely exceptional case where tests or parts thereof must be subcontracted, the Structure Manager examines the possibility and opportunity of using subcontractors.

The requirements to be met in such circumstances are:

- a. the subcontracted activity must be entrusted to entities with proven expertise, favouring those
  who have a Quality System compliant with UNI CEI EN ISO/IEC 17025 for testing activities
  and/or UNI EN ISO 9001 for other activities;
- b. for calibration activities, the instrumentation to be calibrated will be sent to a laboratory accredited according to UNI CEI EN ISO/IEC 17025 with consequent issuance of the certificate under ACCREDIA accreditation (or equivalent in terms of ILAC-MRA);
- c. the subcontracting must be communicated to the client and defined in the offer and contractual requirements;
- d. the Structure Manager has the duty to verify the consistency and, where possible, the correctness of the results obtained from the subcontracted activity before delivery to the client. The structure and Politecnico are responsible for the subcontracted results;
- e. requirements relating to the test report or calibration certificate must be respected.

If a structure transfers the requested service or part thereof to another structure belonging to the Politecnico, this is not considered subcontracting. Nevertheless, the principles expressed in points a), d) and e) above remain valid.

Purchase management guarantees that the selection and purchase of supplies and services with a significant influence on the quality of the services provided are compliant with the established requirements. Such conformity is documented before using the supplies and services by way of procedures that define criteria for initial qualification and maintenance of the suppliers, assessment of the supply, acceptance checks upon receipt, testing and storage (where applicable).

The process as a whole follows the specifications and requirements defined in the Regulation on Administration, Finance and Accounting of the Politecnico di Milano (RAFC), prepared based on the legislation in force (Procurement Code, Legislative Decree 50/2016 as amended and supplemented) and it is further specified and substantiated in PQS documents such as:

- Procurement Management (QAS/MGP.01.006).
- Supplier Register;
- assessment of supply (only for suppliers not listed in the University Register) form QAS/FOR.97.001;
- Supplier list (only for suppliers not listed in the University Register) QAS/FOR.07.062.

The structure requesting the purchase is responsible for monitoring the supply and checking upon delivery what is received.



The requirements are communicated to the supplier through documents relating to the supply as indicated in the Procurement Management procedure ((QAS/MGP.01.006).

# 7. PROCESS REQUIREMENTS

## 7.1. Review of requests, offers and contracts

The QAS and affiliated structures plan and develop processes for the implementation of their services.

Each structure, based on its size, timescales and services, plans its activities, taking account of at least the following:

- the Quality Policy;
- client needs:
- the decisions on organisation of the Central Administration areas;
- annual targets;
- the resources available;
- validation and monitoring activities.

The records of this planning are structured in a form appropriate to the individual structure.

In providing their services, the structures that have adhered to the PQS manage the products and/or information owned by clients (including client property and personal data). Therefore, each structure defines the responsibilities for storage and the methods of correct conservation, in order to guarantee that all client property is correctly managed and archived, identifiable and traceable. If the client's property becomes lost, damaged and/or stolen, each structure identifies its own methods for communicating the event to the client and acts in accordance with what is stated in the specific procedures of reference. The Politecnico guarantees the correctness, transparency and promptness of all activities for managing the relationship with users who work to provide services carried out by its structures related to the PQS, including those that may be subcontracted both internally and externally, i.e. experimental activities, calibration, testing, consultation and training (including those with public tender financing, e.g. Lombardy Regional Government managed with forms identified by the client).

Job management guarantees the correct succession of all management operations aimed at precisely defining the request, offer, order and interim review phases, with particular attention to the transparency and confidentiality of the relationships, timely information and prompt communication. It is subject to continuous improvement interventions resulting from the effort to understand present and future customer requests, with the aim of surpassing their expectations.

The management as a whole, including any subcontracted activities, involves the phases to review requests, offers and contracts, the choice of methods, assessment of the necessary skills and any deviations from the contract or modifications thereto once the activity has begun. The aspects indicated above are identified and listed in the following documents:

- Management of calibration activities (QAS/MGP.99.015);
- Management of testing activities (QAS/MGP.07.057);
- Design and development process (QAS/MGP.07.050);
- Regulation for services on behalf of third parties of the Politecnico di Milano.

### 7.1.1. Testing activities

The methods described are applied to all offers issued and orders received by the Politecnico for testing activities. The contents set out below are detailed in the "Management of testing activities" procedure (QAS/MGP 07.057).



Based on the feasibility analysis and depending on the department organisation, the Laboratory Manager is responsible for preparing the offer, which contains at least the following details:

- reference to the request (date, protocol number, etc);
- the activities offered (if there is an agreement with the client to express opinions and interpretations, it is expressly declared in the offer, specifying the opinions and interpretations that have been issued and what they refer to, clearly indicating that this is not an accredited activity. If the client requests a declaration of conformity, the decision rule agreed with the client itself is expressly declared in the offer. The offer also specifies the case where no declaration of conformity is requested. For details, see Sections 7.8.3, 7.8.4, 7.8.6, 7.8.7);
- the relevant technical standard or internal methods used:
- any sampling terms;
- type of samples;
- timescales of execution and delivery of results;
- transportation and delivery terms of samples sent;
- contact details of the Laboratory Manager;
- amount of services requested;
- invoicing and payment timescales and methods;
- any subcontracting to qualified suppliers;
- indications on personal data processing.

The order may be formalised by way of an external document (originating with the client) or an internal document that is nevertheless approved. Within the limits permitted by the RAFC, the document with which an assignment is formalised is at the discretion of the structure, provided that evidence of acceptance of the specified requirements by the parties is recorded.

Upon receipt of the order, the Laboratory Manager or his/her delegate carries out a review to ensure that the specified requirements are compliant with the agreements made in the preliminary contacts and the offer phase and records their outcome (for example, by stamping the order).

The main aspects reviewed are the correspondence of the type of requested service, delivery times, payment timescales and methods, methods of sending and collecting samples.

Any difference between the order/contract and the offer is resolved before starting to execute the services.

If the order is reviewed by the Administrative Secretary, he/she ascertains the correctness of the order, resolves any discrepancies and sends it to the Laboratory Manager for authorisation to proceed with the work.

If the work is to be carried out with deviations from the standard methods or the "list of accredited methods", the test report issued is a Politecnico di Milano report that does not bear the ACCREDIA accreditation logo.

If the order is modified later, records of the agreements made in this regard must be retained. For each modification, the contract review process must be repeated and the modification must be promptly communicated to all personnel involved.

#### 7.1.2. Calibration activities

The methods described are applied to all offers issued and orders received by the Politecnico for calibration activities. The contents set out below are detailed in the "Management of calibration activities" procedure (OAS/MGP 99.015).

Requests may be received by the QAS Technical Secretary or directly by the Sector Manager.

The QAS Technical Secretary and the Sector work together to perform the feasibility analysis, which consists of:



- available resources;
- workloads and competencies;
- general feasibility of the requested activity.

For tariff rate activities, once the timescales and availability have been defined, this analysis may even be done by the person delegated to the activity by the Manager. For calibration requests not present in the rate table, the Sector Manager assesses their feasibility, indicating in the offer to the client any specific management methods, deviations, timescales, etc.

When working with deviations from the standard methods and accreditation table, the certificate issued is a Politecnico di Milano calibration report that does not bear the ACCREDIA accreditation logo. In order to proceed with the issuance of an ACCREDIA certificate, any modification to ACCREDIA-approved methods involves a new verification and approval by ACCREDIA itself. Based on the feasibility analysis, the QAS Technical Secretary records the Sector's approval (even

by telephone) and prepares the offer, which contains at least the following data:

- reference to the request (date, protocol number, etc);
- the activities offered (if there is an agreement with the client to express opinions and interpretations, it is expressly declared in the offer, specifying the opinions and interpretations that have been issued and what they refer to, clearly indicating that this is not an accredited activity. If the client requests a declaration of conformity, the decision rule agreed with the client itself is expressly declared in the offer. The offer also specifies the case where no declaration of conformity is requested. For details, see Sections 7.8.3, 7.8.4, 7.8.6, 7.8.7);
- the relevant technical standard or internal methods used;
- timescales of execution and delivery of results;
- transportation and delivery of instruments sent;
- contact details of the Sector Manager;
- amount of services requested;
- invoicing and payment timescales and methods.

The offer explicitly contains the meaning of the accreditation and, in particular, provides specifications for the accreditation of the activities in the offer (extension and limits of the accreditation with reference to the table). The client's order may be received by post, email or fax, or by telephone for longstanding clients. If the client sends an order without having first requested an offer from the QAS, the Technical Secretary issues the order confirmation document.

Upon receipt of the order, the Technical Secretary carries out a review to guarantee that the specified requirements are compliant with the agreements made in the preliminary contacts and the offer phase. If the outcome is positive, he/she records the date the order arrived on the "job progress status" form; otherwise, he/she contacts the client.

The main aspects reviewed are the correspondence of the type of service requested, delivery times, payment timescales and methods, methods of sending and collecting the objects to be calibrated. Any difference between the order/contract and the offer must be resolved before starting to carry out the services.

At the end of the order review, having confirmed any changes, the QAS Technical Secretary sends the order to the Sector by email or fax as authorisation to proceed with the works.

If the order is modified later, records of the agreements made in this regard must be retained. For each modification, the contract review process must be repeated and the modification must be promptly communicated to all personnel involved.

If a client asks for tests to be carried out with obsolete methods or those that are considered inadequate by the laboratory, the relevant structure, by way of its customer representative personnel, sends a specific communication to the client.

If a client asks for a declaration of conformity to be added to the test report or calibration certificate, the Sector Manager or Laboratory Manager will define the decision rule to be applied (if not already



contained in the specifications or standard) and will reach an agreement with the client as early as the offer/contract review phase. In defining the decision rule to be adopted, the laboratory must consider the associated risk level and inform the client of the same (it will also be indicated on the test report or calibration certificate, see Section 7.8.6 below). Such assessment is not necessary if the decision rule is imposed by the client or contained in regulations or regulatory documents to which reference is made.

Any deviations related to the testing/calibration activities are managed as indicated in Sections 7.1.1. and 7.1.2 above. In assessing the deviations between what is proposed to the client and what the client requests, the laboratory also assesses the impact that this may have on the laboratory's integrity and the validity of the results and agrees with the client on how to proceed. In the case of deviations with respect to the contract, it is the responsibility of the Sector/Laboratory Manager to assess their impact on the activity and inform the client. For substantial variations, the Sector/Laboratory Manager asks the client to accept the changes before proceeding with the activity. The Sector/Laboratory Manager will communicate the approved changes to the contract to the relevant personnel involved in those activities.

For changes relating to activities already in progress, the Sector/Laboratory Manager informs all personnel involved of changes that may affect the activity already performed and those that still need to be performed. This communication may be sent by email and/or by changing the documents pertaining to the activities.

The laboratories cooperate with their clients both to define the tests/calibrations to be carried out and in the execution phase, allowing the clients themselves (subject to a request made to the Sector/Laboratory Manager) or their representatives (or representatives of their clients) attend at the tests

The laboratories assess the feedback from the client during the laboratory management review, through information received from clients.

All records relating to offers, contracts and exchanges of information with the client are stored as "quality system records" as described in Section 8.4 of this manual and in the quality system specifications for the various activities.

# 7.2. Selection, verification and validation of methods

#### 7.2.1. Selection and verification of methods

The laboratories accredit the tests/calibrations using recognised methods (UNI national standards, Regulations and Decrees-Laws, etc. and international standards EN, ISO, ASTM, etc.).

If internal methods are to be accredited, these methods will be subject to validation as described in Section 7.2.2 below.

The Structure Manager provides laboratory personnel with all methods of interest both for the tests and calibrations and for accessory activities.

In each structure/laboratory, the personnel instructed by the Sector/Laboratory Manager verify the issuance of new methods of interest for laboratory activities, and the updating of those that exist, and communicates this to the managers of the various activities. As part of their responsibilities and the internal organisation of the various sectors/laboratories, these personnel prepare/review the internal testing and/or calibration procedures such that the sector/laboratory has sufficiently detailed and comprehensive operating documents for the correct and univocal application of the method at the laboratory by all authorised technicians.

The Structure/Laboratory Manager informs clients of the methods adopted by the laboratory in the offers or contracts or by way of internal communications for internal clients.



The laboratories principally and preferably adopt standardised test methods (national or international). They prepare internal methods when there are no standards or follow specific client requests and requirements. If they do not refer to standardised methods and are to be accredited, internal methods are subject to validation activities and the respective records are retained as described in Art. 7.2.2 below. For all accredited methods, specific procedures and/or instructions exist regarding choice and applicability (if not already specified exhaustively in the method itself), as well as the associated uncertainty, the instruments used and any information on the performance of tests/calibrations and the checks to be made. When a standardised or official method provides indications for the performance of the method (such as data on repeatability, reproducibility, accuracy, etc.), the laboratory that applies it checks that its performance is compatible with the performance indicated. The laboratory must check that it maintains this performance over time and, in the event the method is revised by the issuing body, the laboratory repeats the checks insofar as is necessary and applicable.

If the Sector/Laboratory identifies the need to develop an internal method, the activity is assigned by the Sector/Laboratory Manager to personnel with suitable expertise and the necessary resources. These personnel prepare development plans that include phases dedicated to periodic reviews so as to guarantee that the initial objectives and client requirements are satisfied. The development plan is also approved upon each modification.

For activities under ACCREDIA - DT accreditation in particular, the methods used by the individual sectors are approved by ACCREDIA - DT itself.

For the methods developed, the laboratory involved is responsible for managing and archiving all documentation, highlighting the preparation of the method and its validation, and for archiving all documentation sent to the client relating to the method developed, as well as for promptly informing the client (if applicable) of all problems that arose during the validation and any situation that may alter the objectivity of the results.

Any deviation that may occur during activities to develop a method is recorded by the laboratory personnel. Any deviation, once identified and documented, is analysed by competent personnel to assess its acceptability and technical justification (if the method in development is intended for a specific client, communication is given thereof and approval is requested before issuing the document). The deviation is only authorised after a positive assessment by the person responsible for development.

### 7.2.2. Validation of methods

For the use of non-standardised (regulated) methods, relating, for example, to the need to test new products/materials or the need to use new instruments and new equipment, the relevant structure/laboratory will establish both the operating methods and the validations to be adopted in the method development documents. The sectors/laboratories validate all methods developed internally and those that are standardised but used outside the established scope of application (for example, applications on different matrices or to expand the fields of measurement) or modified in any other way. The validation is carried out based on the expected application of the method and the field of use. In the method development planning phase, each person responsible for developing a method establishes the procedures to be used for the subsequent validation phase (see Note 2 of ISO/IEC 17025:2017 for further details).

Any change made to a validated method is verified by the issuing structure/laboratory to assess its influence on the original validation and the validation will be repeated completely or partially as necessary. All choices, motivations and results of the re-validations are stored with the re-validated method.



In validating the methods, the structure/laboratory considers the performance characteristics to be validated so as to be able to issue a "validation declaration" (for the planned use) which takes into account clients' requirements and the motivations and requirements for the method being developed and validated.

The structure/laboratory retains all records of the method development, the verifications, reviews and validations (and re-validations) carried out and the respective "declarations of validation" issued in accordance with the "Validation of methods as part of experimental activities" instruction (QAS/OPI.07.058).

# 7.3. Sampling

Laboratories at the Politecnico perform the sampling explicitly requested by and agreed with clients. Documents relating to sampling consider the factors that may influence the validity of the subsequent results and ensure that such factors are adequately known and recorded (and minimised insofar as possible) and that all information related to the methodology, plans and deviations is recorded. In defining the sampling method to be adopted, the person responsible for the activity prepares the sampling plans with consideration for the statistical methods applicable to the activity deriving from both specific rules and general principles. Such aspects are indicated in the plans or prepared sampling procedures. These documents are also provided to personnel so that they are available when performing the sampling activities. The sampling method and procedure contain at least the information relating to the method of selecting the samples or sites to be sampled, the sampling plan and the preparation and treatment (and storage) activities for the sample taken, in such a way as to obtain a suitable sample for subsequent testing or calibration activities.

The person responsible for the job/activity plans the sampling activity, communicating it to the technicians together with the methods (and any internal procedures prepared) and sampling plans. The technicians:

- prepare the material and equipment/instruments/devices necessary to perform the sampling in accordance with the sampling rules and worker safety;
- verify that all material is available to carry out the sampling and to correctly identify and transport the samples (for example, refrigerated cells);
- receive specific operating instructions on how to perform correct sampling (including information that must be provided together with the sample) based on standardised and/or internal methods.

If the sampling is not carried out by the Politecnico sector/laboratory but may affect the result of a test or analysis, when preparing the offer or signing the contract, the person responsible for the job/activity delivers the operating instructions to the clients dealing independently with the sampling and remains available to provide support and clarifications (the sampling is usually performed against standardised methods specified in the offer phase).

Sampling carried out by laboratory personnel is recorded in specific sampling reports delivered together with the samples in the acceptance phase. These reports indicate all necessary information and are then included in the test reports (see Section 7.8 below), including:

- reference to the sampling methods used (and, if applicable, to the internal procedure);
- date and time of sampling;
- identification details and, if appropriate, description of the sample (e.g. number, quantity, name):
- identification of the personnel who performed the sampling;
- identification of the equipment used (insofar as necessary);



- environmental or transportation conditions;
- diagrams or other equivalent means to identify the sampling location, when appropriate and required;
- deviations, additions or exclusions with respect to the method and sampling plan.

Samples arriving at the laboratory are "awaiting acceptance" and are stored in specific, identified areas (if necessary also refrigerated) specified for the storage of unsuitable samples or those awaiting a decision. As far as possible, these areas are separated from the accepted samples and are nevertheless clearly identified.

# 7.4. Handling of objects subject to calibration

The "Management of Testing activities" (QAS/MGP 07.057) and "Management of Calibration activities" (QAS/MGP 99.015) procedures describe the details of activities for testing/calibrating objects/samples.

According to the structure organisation and specific procedures, the Laboratory Manager, Technical Testing Manager or Testing Technician are responsible for accepting the samples and assigning the tests planned for each sample based on the contents of the contractual documents.

Records are kept of the outcome of checks and controls, any non-conformities detected and agreements made with the client. Records of these activities are stored in accordance with the "Management of findings" procedure (QAS/MGP.07.055).

Each sector/laboratory prepares specific spaces and areas for storing samples/objects subject to testing/calibration so that both physical spaces and separations are suitable for avoiding contamination or confusion, and where necessary, the environmental storage conditions avoid any deterioration or degradation of the samples/objects.

Each laboratory and Metrology Sector keeps an updated record of samples which indicates all information relating to the samples received and their treatment within the laboratory or metrology sector, as described in the following sections.

All incoming samples are uniquely identified by way of initials (where present, the serial number is sufficient) so as to guarantee their traceability. Depending on the type of sample, the initials are applied using indelible ink directly on the sample or by way of an identification label. If necessary, each sector/laboratory prepares detailed procedures to transfer the identification information when aliquots or parts of samples/objects are taken for the tests/calibrations to guarantee traceability. These initials are also indicated in the samples record.

As well as guaranteeing identification and traceability, the application of initials to the samples/objects must allow the sample/object to be made anonymous when possible, guaranteeing the best confidentiality and impartiality during subsequent activities.

When the samples are received, preliminary checks are performed (conformity with the delivery note and/or order).

Thereafter, the samples must undergo technical verification (dimensional parameters, technical characteristics, etc.) to ascertain their suitability for the testing/calibration in accordance with what is agreed with the client or required by the method.

Any deviations identified in the sample with respect to the expected requirements must be promptly analysed and, based on the type of non-conformity identified and agreements with the client, it is possible to:

- return the sample and request its replacement;
- accept the sample with reserve, indicating the actual characteristics of the sample received on the testing/calibration report or calibration certificate;
- modify the sample to make it adequate for the testing/calibration activity it is subject to, following agreement with the client.



Samples/objects that require special environmental storage conditions are kept in the rooms/areas specifically prepared by the various sectors/laboratories and the instruments used for monitoring the respective conditions are managed as laboratory "equipment" in accordance with Section 6.4 above.

### 7.5. Technical records

Records are documents that report data relating to the processes performed by structures adhering to the PQS and by the QAS itself. They allow for assessment of conformity with the requirements and the effective operation of the PQS. They may be either internal or external in origin and be on paper or IT media.

The "Documentation Management" procedure (QAS/MGP.07.054) contains indications relating to management activities for quality records (including technical records).

The records are also kept with respect for the methods requested by the client (see, for example, financed activities).

Records are available from both the QAS and structures adhering to the PQS. Some records relating to general issues are stored by Central Administration, for example, for personnel management, they are stored at Human Resources and Organisation.

The methods described apply to the quality registration documents relating to suppliers and to client documents and data.

Records are documents that indicate results or provide evidence of the activities performed. They allow all factors that may affect the results of the activities to be traced, thereby ensuring that the activities can be repeated in conditions as similar as possible to the original ones or audit activities can be performed. For each activity deemed critical, the required records are defined in the relevant procedures.

The Politecnico guarantees the storage of documentation relating to the PQS, including records, for a minimum of 5 (five) years. An exception is made for documents subject to different requirements (e.g. documents regarding CE marking of construction products) and technical documents relating to accredited testing and calibration activities (certificates, reports, records of environmental conditions, calibration and testing data, etc.), which must be stored for at least 10 years.

The archives of each structure/laboratory may be managed on paper and/or electronically.

Each structure/laboratory has its own archive, located in a suitable environment to avoid deterioration or damage and to prevent losses. The archives are located in secure, private places accessible only to authorised personnel.

The issuing structure/laboratory, by way of the local QAM, must promptly identify and segregate obsolete documents with a view to preventing their involuntary use, at the same time distributing the updated edition to the corresponding controlled distribution list or immediately communicating to said list that the validity has ended.

If corrections are made to the paper records, they will be transcribed close to the original crossedout data (not deleted) and signed by the person making the corrections.

Corrections to IT records are not permitted except by producing a new document with an updated revision index (and suitable information to trace the person who made the change and when). The original files and IT data and those re-issued with the corrections/changes are retained. Where technically possible, the reasons for the changes/corrections made are also recorded.

### 7.6. Assessment of measurement uncertainty

Each person designated by the structure/department assesses the uncertainty of the instruments and equipment used at the laboratory according to the criteria indicated in the guidelines "Estimate of measurement uncertainty as part of experimental testing and calibration activities" (QAS/GL.02.012). The specific methods of calculating the measurement uncertainty of each test



and calibration are indicated in the respective detailed operating and technical documents of the department.

Based on the type of activity (testing/calibration), the designated Manager identifies the uncertainty of the method calculated based on all factors that may affect the test/calibration result in order to determine both the global uncertainty of the method and the contributions of the individual concomitant factors (such as instruments, measured samples, sampling, preparation, measurement execution, environmental factors, human factors, interpretation of results, etc.). The calculated values are reported on technical documents prepared to support the interpretation and use of official and standardised methods, or on specific calculation sheets attached to the method procedures for cases where it is necessary to calculate the uncertainty of the result upon each testing/calibration activity.

If a recognised testing/calibration method gives indications regarding the sources of uncertainty, the laboratory will use them to assess its testing/calibration uncertainty. Likewise, if the official or standardised method indicates criteria or methods to estimate uncertainty, the laboratory will follow them.

For each calibration method, the Manager designated by the structure/department identifies the uncertainty of the method calculated based on all factors that may affect the test result in order to determine both the overall uncertainty of the method and the contributions of the individual concomitant factors (such as instruments, measured samples, sampling, preparation, measurement execution, environmental factors, human factors, interpretation of results, etc.). If the method shows uncertainty and the laboratory wishes to use those data, it must assess the repeatability with respect to the data indicated on the method in advance. In this case, the laboratory will use the reproducibility value of the method only after verifying that it falls within the criteria of repeatability and is in comparable conditions.

# 7.7. Assurance of validity of results

The Sector/Laboratory Manager or the Testing/Calibration Technical Manager prepares procedures for monitoring the validity of the results.

The monitoring is planned and re-examined and includes:

- regular use of certified reference materials and/or control of internal quality using secondary or internal reference materials;
- participation in interlaboratory comparison programmes;
- repetition of tests/calibrations using identical or different methods;
- performance of new tests/calibrations on the objects stored;
- correlations of the results between different characteristics of an object;
- use of control charts for monitoring the trend of measuring activities;
- interim checks on the instrumentation or use of alternative instrumentation/equipment;
- tests on unmarked samples:
- review of results obtained.

The data are analysed and if shown to be outside the predefined criteria, planned actions are adopted to correct the problem and prevent incorrect results from being reported, in accordance with the "Management of findings" procedure (QAS/MGP.07.055).

Sectors/laboratories also monitor their performance by way of comparison with other laboratories and they manage the proficiency testing (PT) and interlaboratory comparisons (ILC) in line with ACCREDIA documents. In particular, for the participation in PT/ILC and the choice of organisations to rely on, the following criteria are applied:



- Organisers of interlaboratory proficiency testing (PT) accredited by Accreditation Bodies signatory to mutual recognition agreements on the EA or ILAC level for calibration purposes;
- National Metrology Institutes and Designated Institutes signatory to the multilateral agreement in the field of CIPM MRA (for example, INRIM and ENEA-INMRI in Italy);
- ISO 17043 accredited organisers of interlaboratory proficiency testing (PT)
- Participation in interlaboratory comparisons (ILC) other than interlaboratory proficiency testing.

For participation in PT and ILC, the accredited sectors/laboratories also operate in accordance with the applicable Accredia documents, including RT-08 for testing laboratories and RT-36 for calibration centres.

If the activities described above present results that do not meet the established criteria, the sectors/laboratories apply the provisions of the "Management of findings" procedure (QAS/MGP.07.055) to undertake the appropriate actions to avoid producing incorrect results.

Assurance data on the validity of the results are analysed precisely in the records indicated in the procedures of the various sectors/laboratories and are nevertheless assessed on the management review as input for improvement.

## 7.8. Presentation of results

#### 7.8.1. General information

In order to streamline the activities and contents of the documents, the sectors/laboratories adopt the following method to identify the documents issued:

- Test report: document setting out the results of tests that have been carried out on the sample, the method, testing uncertainty, requirements indicated in point 7.8.2 and 7.8.3 (and, if relevant, 7.8.5) of ISO/IEC 17025 and which will contain the ACCREDIA symbol for the accredited tests. This document may be signed by the Department Head, Scientific Director, Laboratory Manager or Testing Technical Manager and possibly by the Testing Technician or equivalent figure defined by the structure itself and approved by Accredia DL;
- Test conclusions: document that refers to several test reports and illustrates the conclusions reached following the analyses made, judgments of conformity/suitability, summary tables, etc. This document is signed by the Structure Manager;
- Calibration certificates: documents setting out the results of instrument calibrations, the method, calibration uncertainty, requirements of points 7.8.2 and 7.8.4 (and, if relevant, 7.8.5) of ISO/IEC 17025 and IO-09-DT, and which contain the ACCREDIA symbol only for accredited calibrations.
- The certificate is issued in digital format (.pdf) and is signed (digitally) by the Sector Manager (Deputy Manager for the specific quantity) in the capacity of Technical Direction (Approving Officer). For specific quantities, the position of Technical Director may be held directly by the LAT Centre no. 104 Manager. In this case, the certificate is signed by the Technical Operator digitally, with wording to this effect on the second page.
- Calibration reports: these are documents setting out the results of the calibrations of the instruments, the method, calibration uncertainty and requirements of Sections 7.8.2 and 7.8.4 of ISO/IEC 17025. The calibration report does not contain the ACCREDIA symbol but only the mark of the Politecnico di Milano, nevertheless guaranteeing reference to the national/international samples used. These documents are signed by the Sector Manager and contain the signature of the Metrological Manager on the first page.



The documents described above (excluding the test reports) thus present the relevant information for the purposes of comprehension and use of the results, thereby avoiding, insofar as possible, incorrect interpretation by the client.

The layout of the test report, calibration certificate or calibration report is designed to prevent tampering by the client, thereby avoiding improper use of the report/certificate and to identify any non-accredited tests (by way of explanatory note).

For all calibration activities accredited by the LAT Centre no.104, only calibration certificates with the ACCREDIA mark are issued.

Details of the preparation, verification, approval, archiving and transmission of test reports and calibration certificates are indicated in the "Management of Testing activities" (QAS/MGP 07.057) and "Management of Calibration activities" (QAS/MGP 99.015) procedures.

The Manager who signs the documents cited above approves the results contained in the document together with all information requested by the client and involved in the testing/calibration methods and the information necessary for the correct interpretation of the results themselves. All documents issued are retained as "technical records" as specified in this manual.

The testing and calibration laboratories do not present the results in simplified form. At the client's request, the testing laboratory may supplement the test reports with summary or comparative tables, but these do not replace the sending of the test reports.

### 7.8.2. Common requirements for reports (testing, calibration or sampling)

With regard to the contents of test reports and calibration certificates, see Sections 7.8.3 and 7.8.4 below.

The laboratories clearly identify the data provided by the client on the documents issued (reports/certificates).

If the data provided could influence the validity of the results, the test report will indicate the phrase "Data provided by the client: the laboratory declines any liability in this respect".

If, due to analysis upon arrival, the laboratory considers the samples to be submitted for testing or the calibration instruments to be non-conforming, it immediately informs the client. If the client provides instructions to proceed with the experimental activity, the test report/calibration certificate will clearly indicate the non-conformity of the object submitted for testing/calibration with the specification that the test/calibration was carried out at the client's express request and the results reflect what emerged from the testing/calibration.

### 7.8.3. Specific requirements for test reports

The test report is prepared by the technician or the Testing Manager/Technician by completing the specific format based on the test data recorded by the technicians. The contents of the test report are:

- the wording "Test Report";
- identification details of the laboratory;
- client name and address;
- type of tests;
- sequential number of the test report and number of pages (on each page of the test report);
- description/identification of the sample;
- in relation to sampling:
  - o if carried out by the client (wording to be specified on the test report): only data provided by the client are indicated, (specifying that they are "data provided by the client"), including, if critical for the validity or use of the results:



- sampling date;
- references to the sampling plan and to the method (even if the activity is carried out by another body/entity at the client's behest);
- o if carried out by the laboratory: the data relating to sampling may also be indicated in a sampling report and on the test report. In both cases, the data recorded with regard to sampling are (in accordance with point 7.8.5 of ISO/IEC 17025):
  - date and time of sampling;
  - unique identification of the item or material sampled;
  - location of sampling, including any diagrams, sketches or photographs, etc.;
  - identification of the person in charge of sampling (only in the sampling report);
  - reference to the sampling plan and/or sampling procedures/methods;
  - details of the sampling environmental conditions when relevant;
  - details of the characteristics of the sample at the time it was taken (if relevant for the tests);
  - any information that may be necessary to assess the measurement uncertainty;
- date of receipt, start and end date of the tests and issue date of the test report;
- test methods used:
- indications of the method accreditation status. For non-accredited parameters/results, indicate a (\*) next to the method and wording at the bottom of the page: "Test not accredited by ACCREDIA" in the same font, format and size as the result;
- any deviations from the method;
- results of the tests accompanied by measurement unit and any supporting documents;
- declaration of the measurement uncertainty (only for accredited tests);
- the required signatures;
- declarations of conditions of validity of the report;
- rules on non-reproducibility of the report or parts of it without authorisation;
- declaration that the results refer only to the objects tested;
- when applicable or requested and defined in the contractual phase with the client, declaration of conformity/non-conformity with the requirements specified in the applicable standards/legislation (when they explicitly indicate the acceptability limits). In this case, the laboratory will also indicate the "decision rule" applied and the respective associated risk level (see also Sections 7.1 and 7.8.6 of this manual);
- when applicable or requested and defined in the contractual phase with the client, opinions and interpretations, if not accredited, will be inserted under the wording "opinions and interpretations not accredited by ACCREDIA" (see also Sections 7.1 and 7.8.7 of this manual);
- clear identification of results originating from external providers (if applicable).

For test reports issued with the ACCREDIA mark, the laboratory also complies with all requirements contained in the documents RT-08 and RG-09 in force.

Test reports/conclusions are usually sent to the client after the invoice is paid. If payment times are accepted during the order review phase that differ from payment upon receipt of the invoice, they are sent when the invoice is issued.

In the case of particular requirements expressed by clients and agreed with the Laboratory Manager, the test reports/conclusions may be sent even before the invoice has been paid.

The test reports/conclusions are sent in original or electronic format (scan of original test reports or test reports in PDF format with electronic signature). Any documents may be sent in advance by fax in cases of particular need expressed by the client; however, they do not replace the original in any way. Test reports/conclusions are sent in accordance with the rules defined by the structure.



### 7.8.4. Specific requirements for calibration certificates

The calibration certificate is prepared by the technician or Calibration Technical Manager by completing the specific format based on the data recorded by the technicians. The contents of the calibration certificate are:

- Title:
- Name, logo and address of Politecnico di Milano Quality Assurance Service;
- Unique identification with the following format: LAT Centre no. 104 nnnn/yyyy for ACCREDIA certificates, where nnnn indicates a four-digit sequential number within the current calendar year and yyyy indicates the year in full;
- Client name and address:
- Recipient name and address;
- Identification of the method used;
- Unique identification of the instrument being calibrated;
- Date of receipt of samples, if significant and/or critical;
- Environmental conditions that influence the calibration results;
- Results accompanied by appropriate measurement unit and associated measurement uncertainty;
- Evidence of traceability of the measurements;
- Declaration of conformity with a defined metrological specification or some of its points. In this case, the laboratory will also indicate the "decision rule" applied and the respective associated risk level (see also Sections 7.1 and 7.8.6 of this manual);
- Opinions and interpretations, if accredited and requested and defined in the contractual phase with the client (see also Sections 7.1 and 7.8.7 of this manual and specific ACCREDIA rules in RT-25 and IO-09-DT);
- Name and signature of the person that authorises the issuance;
- The declaration certifying the applicability of the results only to the instrument subject to calibration;
- Any deviation from the calibration method.

The calibration certificate is issued in digital format (.pdf) and is signed (digitally) by the Sector Manager (Deputy Manager of the specific quantity) in the capacity of Technical Direction (Approving Officer). For specific quantities, the position of Technical Director may be held directly by the LAT Centre no. 104 Manager. In this case, the certificate is signed by the Technical Operator digitally, with wording to this effect on the second page. In case of emergency, the Certificate may be signed by the LAT Centre no. 104 Manager who, in this case, acts as Technical Director (Approving Officer) in lieu of the Deputy Manager of the specific quantity. For calibration certificates issued with the ACCREDIA mark, the laboratory also complies with all requirements contained in the documents IO-09-DT, RT-25 and RG-09 in force.

The service ends with the issuance of the invoice and payment of the fee.

Calibration certificates are usually sent to the client after the invoice is paid. If payment times are accepted during the order review phase that differ from payment upon receipt of the invoice, the certificates are sent when the invoice is issued. In the case of particular requirements expressed by the client and agreed with the Sector Manager, the certificates may be sent even before the invoice has been paid.

The Politecnico Calibration Centre does not perform sampling; such aspects are therefore not applicable to the LAT Centre no. 104 and the respective information is not present or indicated on LAT Centre documents.



The calibration certificate does not contain information relating to the calibration interval. In addition to the calibration certificates, the laboratory affixes or provides labels following the calibration which contain the following items:

- company name and laboratory accreditation number;
- identification of the instrument/sample;
- date of calibration;
- number of the certificate issued following the calibration.

### 7.8.4.1 Calibration reports (without ACCREDIA mark)

The calibration report is prepared by the technician or Calibration Technical Manager by completing the specific format based on the data recorded by the technicians. The contents of the calibration report are:

- Title: Calibration report
- Name, logo and address of Politecnico di Milano Quality Assurance Service;
- Unique identification PQS/nnn/yyyy, where nnn indicates a three-digit sequential number within the current calendar year and yyyy indicates the year in full;
- Client name and address;
- Identification of the method used;
- Unique identification of the instrument being calibrated;
- Date of receipt of samples, if significant and/or critical;
- Environmental conditions that influence the calibration results;
- Results accompanied by appropriate measurement unit and associated measurement uncertainty;
- Evidence of traceability of the measurements;
- Declaration of conformity with a defined metrological specification or some of its points;
- Name and signature of the person that authorises the issuance;
- The declaration certifying the applicability of the results only to the instrument subject to calibration;
- Any deviation from the calibration method.

The calibration report is issued in paper format (duplicate copy) and is signed by the Sector Manager on every page.

The service ends with the issuance of the invoice and payment of the fee.

Calibration reports are usually sent to the client after the invoice is paid. If payment times are accepted during the order review phase that differ from payment upon receipt of the invoice, the calibration reports are sent when the invoice is issued.

In the case of particular requirements expressed by the client and agreed with the Sector Manager, the certificates may be sent even before the invoice has been paid.

### 7.8.5. Presentation of information relating to sampling - specific requirements

The specific requirements to be indicated on test reports relating to sampling are detailed in Section 7.8.3 above.

The Politecnico does not accredit sampling alone and does not carry out only sampling; it therefore does not issue "Sampling Reports". If it does issue them, it will comply with the provisions of ISO/IEC 17025 points 7.8.2 and 7.8.5.



### 7.8.6. Formulation of conformity declarations

At the specific request of the client, declarations of conformity may be issued in the test results or calibration certificates. In this case, the sector/laboratory must agree with the client which decision rule to apply for formulating the declaration of conformity (see Section 7.1 above). To establish the decision rule, the Sector/Laboratory Manager adopts the following method:

- decision rule established or imposed by the client: no assessment is made of the associated risk level and it is applied as requested, subject to verification of its compatibility with the type of activity subject to testing/calibration;
- decision rule established by a standard, law, regulation and accepted by the client in the contractual review phase: no assessment is made of the associated risk level and it is applied as set out in the document of reference;
- decision rule proposed by the laboratory to the client: the Manager assesses if it is possible to use a rule established by standards or regulations (and if so, it does not perform any assessment of the associated risk level); if it is not possible, it proposes a decision rule to the client, also indicating the risk level associated with said rule (for example, using the concept of guard band expressed in ILAC-G8 or the criteria expressed in the ISO/IEC 98-4 guide or in standard UNI EN ISO 14253-1).

The laboratory does not report declarations of conformity on test reports or calibration certificates unless the request is expressly made by the client and inserted in the offer/contract review phases (see Section 7.1 above) or is envisaged by the test/calibration standards. In this case, the laboratory will apply the decision rule established with the client for formulating the declaration of conformity. Any declaration of conformity relating to the calibration certificates is indicated in compliance with the ACCREDIA DT IO-09-DT document.

If declarations of conformity are indicated on the test reports or calibration certificates, it will clearly indicate which results they refer to, which parts are met (conformity) and which are not, and the decision rule applied with the respective risk level, if relevant.

### 7.8.7. Presentation of opinions and interpretations

If the sectors/laboratories accredit the formulation of "opinions and interpretations", such opinions and interpretations will be indicated on the test reports and calibration certificates in accordance with ACCREDIA requirements (RT-08, RT-25 and IO-09-DT) and in such a way as:

- To be formulated only by personnel authorised by the Department Head;
- To clearly identify that these are "opinions and interpretations" formulated in such a way as to avoid implying any approval by ACCREDIA of the calibration results or the opinions and interpretations;
- To be formulated such that they are not confused with product certifications (ISO/IEC 17065), inspection reports (ISO/IEC 17020) or declarations of conformity;
- To identify the bases on which they are formulated, with documentation of the same and identification of any data provided by the client and used for such formulation (this aspect will also be highlighted on the reports/certificates);
- To be based on (and clearly correlated with) the results obtained from the objects subject to testing/calibration.



### 7.8.8. Correction of reports

Test reports/calibration certificates/calibration reports may not be modified after being sent to the client. To correct and/or supplement the data contained therein, a new document is issued, indicating the reason for the change.

If changes to the test reports are required, the Laboratory Manager agrees the changes/additions to be made and the motivations adduced with the Testing Technical Manager. An amendment to the test report may be made:

- following the request for corrections and/or additions by the original recipient considered to be motivated and valid by the issuer;
- if laboratory personnel identify an error after issue and shipping.

The amendment constitutes a new test report to all effects which is codified with a new test report number. Furthermore, all pages carry the wording "Amendment to test report no. nnn/yyyy of dd/mm/yyyy" and the changes are highlighted by means of underlining and/or crossing out, including, where appropriate, the reason for the change. The "date" field of the new certificate should be completed with the actual issue date of the amendment.

In particular (see RT-08 rev. 04 Accredia) the test reports must be corrected and reissued in the case of:

- incorrect or misleading use of the Accredia mark or reference to accreditation
- errors in the test results
- any other deficiency or error that may involve improper use of the test report by the client or third party, or compromise the correct understanding of the test results by the client, a third party or the authority.

When a test report containing this type of deficiency is identified, it must be managed as a non-conforming activity, that is, involving the re-examination of all test reports issued, tracing, correcting and reissuing reports affected by the same deficiencies.

Calibration certificates may not be modified after being sent to the client. To correct and/or add to the data contained therein, a new certificate is issued. If changes or additions to the contents of the calibration certificate are required, the Sector Manager agrees to the changes and issues a new calibration certificate.

In accordance with the ACCREDIA RT-25 document, if it is necessary to correct what is stated on a calibration certificate for any reason:

- the QAS withdraws the certificate that presents anomalies;
- the Sector issues a new certificate with a new number provided by the QAS and the wording "replaces certificate no. ... dated....";
- the QAS archives the withdrawn certificate with the wording "replaced by certificate number ...".

Calibration reports may not be modified after being sent to the client. To correct and/or supplement the data contained therein, a new report is issued. If changes or additions to the contents of the calibration report are required, the Sector Manager agrees to the changes and issues a new calibration report.

# 7.9. Complaints

Complaints are managed in accordance with the "Management of Findings" procedure (QAS/MGP.07.055) and, as with findings from internal audits, are drafted and recorded by the structure that receives the complaint directly from the web platform of the Quality Assurance Service.



Verbal complaints may be received by telephone, email or another type of oral and/or digital communication as well as through a visit to the premises of the interested party.

At least annually, the QAM or personnel delegated by the Department obtain feedback from clients (for example, by way of interviews or questionnaires) to learn more about the level of satisfaction with the activities performed.

Upon request, the complaints management process is communicated to the applicant by the local QAM or by personnel delegated by the Department.

In order to understand its technical or managerial nature, pertinence and criticality, every complaint is analysed at levels that depend upon its type and characteristics, involving the Structure Manager, the Manager of the activity subject to the complaint, the local QAM and the personnel who carry out the activities involved. In collaboration with the local QAM, the LAT/LAB Centre Manager intervenes in managing the technical complaint if this may affect the results of the accredited calibrations or tests, attributing responsibilities depending on the different type.

The local QAM is responsible for implementing the complaints management process by executing (or having executed) all identified actions considered adequate for managing (treatment and corrective actions) the complaint itself.

The local QAM, with the collaboration of all personnel involved, is responsible for collecting and verifying all information necessary to validate the complaint.

The Manager of the LAT Centre/Laboratory (in collaboration with the local QAM) is responsible for communicating both the receipt of the complaint and periodic communications (insofar as they are appropriate) to the complainant on the status of actions taken following the complaint and their outcome.

Before communicating the final outcome of the complaint to the complainant, the local QAM, at the request of the LAT Centre/Laboratory Manager, has the case relating to the complaint reexamined by personnel not directly involved in the activities in question or the actions taken. This may be done by personnel external to the sector/laboratory with personnel of the QAS or other sectors/laboratories.

When necessary, the LAT Centre/Laboratory Manager (in collaboration with the local QAM) emails the relevant information relating to the conclusions of the complaint. If possible, the local QAM communicates the closure of the complaints handling process to the complainant.

All internal findings opened by the structures adhering to the Politecnico Quality System are managed on the web platform and are accessible across structures.

The Quality Assurance Service directly monitors these as part of the LAT Calibration Centre no. 104, along with findings from all structures deriving from client complaints, supervising that they are correctly managed and adequately closed.

Should the complaint be of common interest to all structures, QAS will send them an informational notice containing the full means of managing the complaint by the structure that received and dealt with it.

# 7.10.Non-conforming activities

The Politecnico defines non-conformities (NC) as a deviation from the specified requirements in the executive activities or in the characteristics of materials, products, processes, instruments and tests. Deficiencies in the documentation which render the quality of the activities or tests unacceptable or indeterminate are defined in the same way.

The methods described are applied to all non-conformities identified in the tests performed (including sampling), calibrations of instruments, the documents issued (such as test reports and calibration certificates) or the services provided by the Quality System or generated by suppliers.



The management of non-conformities thereafter is described in the "Management of Findings" procedure (QAS/MGP.07.055).

The activity guarantees analysis of the findings, viewed as ascertaining factual data validated by objective evidence found in reports, complaints or in any other form, even exclusively verbal (e.g. simple telephone contact).

The origin of a finding may, for example, lie in:

- Client complaint (external or internal);
- Delays:
- Problems:
- Reports;
- Activities that do not conform to the PQS requirements.

The activity also ensures a prompt and effective response to all criticalities that emerge, whether already illustrated in findings or merely potential, developing and documenting appropriate strategies and codifying corrective and preventive actions aimed at resolving and preventing the causes that triggered the negative effect or its potential effect, or improving the service offered as a whole, highlighting its implementation and effectiveness.

In the case of non-conformities (NC) that may affect the results of calibrations accredited by ACCREDIA - DT, the LAT Calibration Centre no. 104 Manager is responsible for defining adequate measures, which may include the suspension of calibration activities and any cancellation and replacement of the certificates issued. Furthermore, the LAT Calibration Centre no. 104 Manager is responsible for communicating the NC and measures adopted to the ACCREDIA DT Technical Secretary.

In the case of non-conformities (NC) that may affect the results of tests accredited by ACCREDIA, the Laboratory Manager is responsible for defining adequate measures, which may include the suspension of testing activities and any cancellation/replacement of the reports issued and their communication to Accredia DP.

The actions taken must always be based on risk levels established by the laboratory.

Whatever its origin, the finding undergoes an initial phase of registration by the person who identified or received it, using the forms present on the web platform of the QAS:

- "Internal Findings" (QAS/FOR.00.007)
- "Findings from internal audits" (QAS/FOR.15.001)
- "Findings from third party audits" (QAS/FOR.12.006)
- "Findings of documentary nature" (QAS/FOR.12.007)

It is specified that all findings must be managed until closed by the structure.

All findings completed and managed by the structure involved are compiled in a cross-sectional list available to all structures. This availability of information is to be considered continuous improvement of the Quality System.

In order to understand their nature, pertinence and criticality, every finding is analysed. The analysis is made at levels that depend on the type and characteristics of the finding, involving the Structure Manager, the manager of the activity subject to the finding, the local QAM and the personnel who perform the relevant activities. The findings are classified as:

• Non-Conformity (NC): failure to meet one or more precise requirements of the PQS that does not compromise the entire management (e.g. the letter of assignment has not been prepared for professor XY; the offer sent to the client does not contain all required specifications).



• Observations: potential failure to meet a requirement of the PQS (e.g. the data collection system must be improved; the internal training plan for collaborator XY must be supplemented).

The findings arising from internal audits are managed in accordance with the "Management of internal quality audits" (QAS/MGP.94.003) procedure, drafted and recorded using the "Management of findings from audits" (QAS/FOR.10.081) form available on the Quality Service web platform.

If the finding is assessed as not pertinent by the Manager of the activity in question or the local QAM, it is rejected, giving motivated communication thereof to the person who raised it (by letter, email or fax, in the case of an external client).

If, on the other hand, the finding is recognised as well-founded, the Manager of the activity in question liaises with the local QAM and assigns it a level of criticality based on the risk analysis, with particular reference to:

- level of actual or potential compromise of the activity involved and, if appropriate, the entire QS applied;
- recurrence and repeatability;
- inciting causes, including any latent causes.

The records described and all documentation are identified, archived and catalogued in accordance with the methods and timescales indicated in the "Documentation Management" (QAS/MGP.07.054) procedure.

If the analysis leads to the need for corrective actions, the activity is managed as stated in Section 8.7 of this Quality Manual ISO/IEC 17025.

For analyses that may involve the suspension of accreditation, the local QAM is responsible for communicating the self-suspension to the officer in charge of interacting with Accredia, managing the actions that follow.

For non-conformities on testing reports/calibration certificates already issued, the laboratory will analyse the reports/certificates already issued which may be affected by such anomalies, implementing the necessary actions.

# 7.11.Control of data and information

The laboratories have hardware and software for word processing and spreadsheets, commercial or ad hoc programs and any personalised routines/calculation forms are prepared and checked before use (recording "validations" of the internal software and/or customisations).

In general, the following SW is considered for managing the activities:

<b>Database Identification</b>	Information and data therein		
Instrument management service	Collects the metrological confirmation data and manages the list of instruments, calibration and maintenance schedule and instrument specifications (including records).		
QAS Website	List of reference documents of the Politecnico di Milano Quality Management System.		
Case protocol (Titulus)	Manages the protocol and archives cases.		
Files for control charts	Control data for quality assurance, test results and calibration (control charts).		
Dedicated software for some instruments	Raw analysis data, test and calibration data.		



Ugov Accounting	Collects data recorded in the accounts relating to jobs and purchases.		
Supplier Register	Collects the data relating to purchases (client details, assessments, etc.)		
Job management software (LPMSC)	Collects data relating to jobs in the Testing Lab for Materials, Buildings and Civil Structures.		

The application can be accessed using a user ID and password authentication (which is known to the system administrator), guaranteeing the uniqueness of the records.

The calculation sheets have cells containing protected formulae so as to avoid alterations or involuntary tampering.

All IT data are archived on the Politecnico servers and are subject to backup procedures. The ASICT area carries out periodic checks on the backup functionality and has prepared specific disaster recovery procedures.

Management of the IT network and programmes used by the laboratories is the responsibility of the departments themselves and the ASICT.

Insofar as possible and necessary, the Department Heads provide the laboratory with manuals for the instruments and the software. Such manuals may be on paper (and therefore physically present near the instruments) or directly viewable as "online help" or as files on the computers themselves. If it is necessary to develop dedicated software or prepare calculation sheets to support the activities performed, the person preparing the software/calculation sheet validates the calculation process of the results, inserting known values for the individual parameters necessary for determining the results, and verifies the entire process, comparing the result obtained from the calculation with what was expected, thereby validating the calculation sheet (protected in the cells containing formulae) and any data transfer. The details of the validation activities are contained in the "Validation of the methods in experimental activities" (QAS/OPI.07.058) instruction.

# 8. MANAGEMENT SYSTEM REQUIREMENTS

# 8.1. General information

The laboratories have decided to document in this Quality Manual the activities relating to its own management system to guarantee conformity with the requirements of ISO 9001, ISO/IEC 17025 and ACCREDIA.

Implementation and organisational changes relating to laboratory activities are formalised in this Quality Manual, the management, operating and technical documents and the internal system documents specifically prepared for activities at the Politecnico and its structures.

The duties and responsibilities of central bodies at the Politecnico and its structures are defined by the Statute, University Regulations and regulations internal to the structures. The functions that interact in the activation, application and improvement of the PQS are described below.

### 8.2. System documentation

The Rector of the Politecnico establishes the policies and objectives of the Quality System in this Quality Manual.

In the document relating to the Quality Policy, the Rector has established:

• respect for the requirements of the Accreditation Body in terms of professionalism and expertise of employees and quality in the performance of tests and calibrations;



- improvement of services provided to clients (internal and external) in terms of performance of the testing, calibration and delivery of the results, defining a maximum time limit for the performance of tests, comprehensibility of the results, providing indications of conformity between the results and values required by the reference standards, visual support graphics for numerical interpretation; technical consultation for any problems identified and/or the results provided;
- respect for the requirements of the certification body in terms of professionalism and quality of the service;
- maintaining high quality in the services provided by Politecnico and its laboratories, in particular:
  - monitoring continuously if possible the analytical performance of personnel and instrumentation;
  - pursuing improvement in analytical and testing performance;
- verifying respect for the requirements of standards UNI EN ISO/IEC 17025, UNI EN ISO 9001 and applicable mandatory regulations, as well as examining any specific problems, which will be conducted as part of periodic planned reviews.

The Quality Policy expressed by the Rector is contained in full below (see document QAS/DOC.01.001).

Since the beginning of the 1990s, Politecnico di Milano has believed and invested in promoting a culture of quality with the aim of improving the management of its activities and performance according to established institutional and strategic objectives.

In this perspective, the promotion of this culture of Quality is interpreted as an organisational tool for improving the efficiency and effectiveness of the University's activities, in particular:

- research activities;
- institutional and non-institutional teaching;
- administrative and customer service activities.

Promoting the culture of quality within the University is therefore important for strengthening the visibility and pervasiveness of quality in research, service and training activities in the departments and central administrative structures. The approach adopted, based on a vision of processes, can facilitate the definition of organisational models which, although different for the various activities (research, teaching and support services), are consistent with the management objectives and facilitate their achievement. Objective planning and monitoring, management of resources and procedures and self-evaluation criteria are important elements of our continuous improvement, playing an increasingly important role in rational and effective management. At the same time, through the culture of quality, we can teach users the principles of attention and, through mechanisms of internal bench-learning, identify good practices that can be exported to other Italian universities, institutions, companies and public administrations, thus enhancing the University's skills and image.

As always and even more so today, these aspects have held great value for the Politecnico di Milano, which is known nationally and internationally as a technical University of excellence. This also includes initiatives to strengthen and recognise the quality of institutional teaching provided by study programmes and scientific research.

As reference standards for its own organisation, the Politecnico di Milano has adopted the ISO 9001 standard for organisational aspects, service delivery and non-institutional teaching, and the ISO/IEC 17025 standard for testing and calibration activities. To strengthen its position and objectify the performance achieved, Politecnico di Milano is also committed to complying with the



requirements of Certification and Accreditation Bodies. The spread of the culture of quality is implemented by involving all personnel in familiarising themselves with the Quality System documentation and implementing its contents and requirements, so employees at every level of competence and function work daily for continuous improvement.

The principles the Management intends to promote at the Politecnico di Milano are as follows: involving people through internal communication and training processes as factor to enable quality of the services provided;

having a vision of a process-based organisation, thereby simplifying the activities carried out by concentrating on achieving the set objectives;

continuous improvement through the use of performance indicators, together with the management of complaints, reports and non-conforming situations.

strengthening and solidifying the centrality of the user and user satisfaction on all levels, thus enhancing and consolidating the University's reputation in the eyes of all stakeholders.

The principles the Management intends to promote at the Politecnico di Milano are as follows:

- involving people through internal communication and training processes, as a factor in enabling the quality of the services provided;
- having a vision of a process-based organisation, thereby simplifying the activities carried out by concentrating on achieving the set objectives;
- continuous improvement through the use of performance indicators, together with the management of complaints, reports and non-conforming situations.

The scope of all activities required by the Politecnico Quality System is to strengthen and materialise the centrality of the user and user satisfaction on all levels, thereby enhancing the reputation of the University in the eyes of all stakeholders.

The Politecnico and all its structures set continuous improvement as the aim of its quality policy, which is implemented by monitoring the indicators and achieving the set objectives.

This Quality Manual cites all management and technical documents/applications that define the details of the technical/managerial activities implemented by the laboratories/structures.

All personnel, insofar as they are responsible, have access to the necessary documentation to carry out the activities and to guarantee the functioning of the Quality System.

# 8.3. Control of quality management system documents

The sections of the Quality Manual cite the management, operating and technical documents that contain details about the technical and managerial activities implemented by the Politecnico for the activities that affect the laboratories themselves.

The complete, updated list of procedures is available for consultation on the platform www.qualita.polimi.it in the section dedicated to the University's Quality System.

The Quality Manual may be reissued every so often by the Quality Assurance Service (QAS) or if the Rector considers it necessary. Within six months of taking office, the Rector chooses whether to share or modify the policy expressed in the Manual.

The Management Representative relies on the QAS to prepare and update the Politecnico Quality Manual, in compliance with the requirements of the standards of reference.

The Quality Policy defined by the Rector, the object of a separate document (QAS/DOC.01.001), is reported in full within this Manual in Section 4.2.2 above.

The current edition of the Manual is indicated by a number (1, 2, etc.) at the bottom of the page, and the changes with respect to the previous edition, whether an addition or deletion, are generally indicated graphically through comments in the margin to the side of the paragraph. If there are



widespread changes following a complete revision of the document, the wording "widespread changes" is stated in the table "*History of revisions*", and the individual changes are not highlighted. The Quality Manual and all system documentation is distributed in both controlled and uncontrolled ways. The Service maintains an archive of all updates to the QMS documentation.

Management of the documentation encompasses all documents that constitute an integral part of the PQS, whether of internal or external origin, on paper or IT format. The purpose is to ensure that every activity is supported by an adequate, updated and complete body of documentation available to the people involved.

In addition to what is defined in this Manual, for the detailed and complete description of the process and for evidence of the actions completed, see the "Documentation Management" (QAS/MGP.07.054) procedure and internal documents such as the "List of current documents".

Management of the documentation encompasses all documents that constitute an integral part of the PQS, whether of internal or external origin, on paper or IT format. The purpose is to ensure that every activity is supported by an adequate, updated and complete body of documentation available to the people involved.

In addition to what is defined in this Manual, for the detailed and complete description of the process and for evidence of the actions completed, see the "Documentation Management" (QAS/MGP.07.054) procedure and the internal documents indicated in the List of current documents.

Documentation management activities involve the following fundamental aspects.

### Input

- a) Requirements envisaged by national or international laws or Politecnico regulations (Statute, regulation of services on behalf of third parties, RAFC).
- b) ACCREDIA requirements (for Metrology Sectors and accredited testing laboratories).
- c) Requirements of financed training activities.
- d) Practice.
- e) Stakeholder requirements and/or needs, both technical and managerial.
- f) Need for communication.
- g) Need for analysis/improvement.

### Process phases

- a) Assessment of preparation and/or modification requirements.
- b) Choice of document type.
- c) Analysis and definition of modifications and respective responsibilities.
- d) Preparation/revision or registration.
- e) Verification.
- f) Approval and issuance.
- g) Distribution/elimination of outdated documents.
- h) Archiving.

### **Output**

- a) Approved document.
- b) Procedure standardisation.
- c) Communication/information/accessibility for pertinent levels.
- d) Records (data).

The methods described apply to all operating documentation and the Politecnico Quality System and, insofar as is applicable, to external documents such as standards and client/buyer specifications/standards.

Politecnico di Milano General Management Staff Operation - Quality Assurance Service



The software used by the structures belongs to the following categories:

- generic commercial software or software created by specific houses for the relevant sector (such as laboratories or certain devices): the software is considered to be validated directly by the producer;
- management software for testing/measuring devices: the software is provided at the same time
  as the instrument/device and forms an integral part of it; the software is validated during
  testing phases (acceptance of the instrument and/or in the pre-calibration phase or verification
  of operation and during periodic planned calibrations), recording the outcome on the
  instrument purchase and acceptance documents and the instrument specifications;
- software created by laboratories or upon laboratory specifications (programmes for calculating test results or uncertainties, customised Excel spreadsheets, etc.): the customisation is validated by the applicant or user of the software through comparative verification of the calculations made by the software and calculations made by other systems (other software, examples based on standards or guidelines, calculations validated manually, results of comparison tests or proficiency circuits, etc.).

The outcome of the controls is archived by each structure. Revalidations with the same methods are planned if the software or operating system is changed (QAS/OPI 07.054 Operational management of IT resources). The validation system is built on the operating instruction "Validation of methods as part of experimental research" (QAS/OPI 07.058).

The Politecnico website is managed by the Communication and External Relations Area which defines the policies.

Each document is verified by individuals competent in the matter in question.

The check is carried out to certify the conformity of the contents with the standards or documents of reference or, in the case of technical documents, performing a critical analysis to certify the conformity of the methods described (testing, calibration, use of instrumentation, etc.).

The signature of approval is affixed by the Structure Manager of the area for which the document is prepared; the Manager authorises its issuance and application of the contents.

The methods for signatures are the following:

Managamant Dugaaduuas	Local QAM	Structure Manager	
Management Procedures	VERIFICATION	APPROVAL	
Operating Procedures	Competent technical personnel	Structure Manager	
	VERIFICATION	APPROVAL	

The operating and technical procedures prepared by the Metrology Sectors of the LAT are verified by the Sector Manager and approved by the Politecnico LAT Centre Manager.

The management procedures prepared by the LAT Metrology Sectors are verified and approved by the Sector Manager.

The operating instructions, documents and forms are verified by the local QAM if they relate to management and by technical personnel if they relate to operations.

The technical procedures of the LAT Centre no. 104 must be approved by ACCREDIA-DT before being applied. The procedures must never be used prior to their approval. With regard to the Quality Manual and management procedures, ACCREDIA-DT has fifteen days to complete the assessment. If ACCREDIA-DT has not provided any type of report in this regard within this period, the Centre may apply the system documentation even without a specific positive assessment by ACCREDIA-DT. The documents that describe a feature of the structure (e.g. organisation chart, duties and minimum requirements, etc.) only bear the approval signature of the Structure Manager.



With respect to need and specific expertise, each structure adhering to the PQS is responsible for drafting, identifying, verifying, approving, distributing and archiving the documentation, including national and international regulations, necessary to correctly perform the activities. Where necessary or required, the structure also promotes and makes any revisions of the documents. For the regulations on testing and calibration methods, the structure QAM, Structure Manager or designated person obtains them from the official issuing bodies, archives them in an area accessible to laboratory personnel interested in the content and performs a periodic validity check.

The PQS documentation prepared and managed by the QAS is available online, in its updated version at www.qualita.polimi.it/.

Notifications about the issue of new documentation or new PQS updates are managed via notices on the Quality Assurance Service web portal or communicated to users at meetings with the Quality Service.

Any distribution of controlled copies of PQS documentation to entities or persons external to the University is adequately recorded by way of specific lists.

The methods of managing documents of external origin are described below.

Documents originating from Politecnico structures not adhering to the PQS: such documents, including regulations, circulars, communications, etc., are identified by way of their title/protocol and date of issue. Regulations, circulars and official communications are managed by the University intranet network which guarantees their control, update and distribution. Documents originating from clients: such documents include, for example, procedures, designs, flowcharts, etc. The person responsible for the identification, storage, distribution and archiving is identified as the manager of the job/project who, at the end of the activity/project, archives all related documentation when not otherwise expected by contractual agreements (for example, when the client requests the return of the documentation provided). The structure also guarantees the confidentiality of such documents by reserving access only to members of the working group involved.

Documents originating from suppliers: such documents, including offers, order confirmations, catalogues, etc., are identified by way of their title/reference number and date of issue and are archived in the purchase file. If the document does not have its own code, it may be codified upon receipt by the structure.

Documents originating from regulatory/certification/accreditation bodies: such documents, including laws, regulations, technical standards, etc., issued by the EC, Italian State, Lombardy Regional Government, Accredia, ISO, UNI, etc., are managed by the local QAM (or other designated individual/person) who guarantees their control and, where necessary, update and distribution.

Updates to the aforementioned type of documentation are guaranteed by the local QAM by way of periodic consultation of dedicated websites (such as http://www.accredia.it; IHS Standards Expert electronic database (standards: ISO, ASTM, UNI). https://login.ihserc.com/login/erc?, http://www.biblio.polimi.it — Access to databases, electronic periodicals, and to suppliers of electronic periodicals available to Politecnico di Milano users; http://www.gazzettaufficiale.it — Laws of the Italian State published in the Official Journal in the last 2 months; http://www.reteambiente.it — Commented environmental regulations, Legal requirements on the environment) and registration for specific newsletters (such as ACCREDIA, Reteambiente, Uninotizie, Italcert).

The updates are communicated by the local QAM (or other designated person), who is also responsible for guaranteeing the removal of outdated documents and, only for documentation issued by the structure, archiving a copy (specifically highlighted as outdated) as maintenance of historical knowledge. Exceptions consist of forms that contain indexes or lists: Every time the list or index requires an update, a new form is completed to replace the previous one, which does not need to be



retained. For forms that act as registration documents on the other hand, the general rule of archiving the replaced copy applies in order to guarantee maintenance of the history.

The Structure Manager or local QAM may prepare a consultation copy for personnel of the areas where the procedures and forms are used. Access to this partial copy of the general archive is authorised by way of a list of names of people who have access to said documentation. The issue and update of the documentation may, in such cases, be communicated to personnel by way of a notice affixed in a visible location or personal communication (email or letter).

Changes to the documents with respect to the previous edition are generally reported graphically, whether they are supplements or deletions, by notes in the margin to the side of the section. If there are widespread changes following the complete revision of the document, the wording "widespread changes" is stated and the individual changes are not highlighted.

Changes "by hand" to the documentation are permitted only for corrections of formal errors, which must be dated and signed by the corrector. Substantial changes to the document or excessive formal corrections lead to the reissuance of the document.

### 8.3.1. Use of the Accredia mark and the Italcert logo

The Accredia mark may be included:

- on commercial, promotional and advertising documents;
- on the pricing method of the LAT Centre and the LAB Laboratory;
- on ACCREDIA accredited test reports;
- on ACCREDIA accredited calibration reports;
- on the outside of the buildings only to identify the LAB Laboratory or LAT Centre sector;
- for calibration sectors, on the label forms as defined by Accredia.

Use of the Accredia mark by LAB laboratories or LAT sectors must be communicated to the Quality Assurance Service. The latter, having compared the document in question with the rules imposed by RG-09 - Regulation on use of the ACCREDIA mark, has ten days to complete the assessment and issue a judgment of conformity. If QAS has not provided any report within this period, the structure may consider the assessed document to be approved. If the document in which the ACCREDIA mark is to be used also reports activities that are not subject to ACCREDIA accreditation, these must be clearly separated.

The use of the ITALCERT logo is optional for PQS structures that have obtained the certification. If the structure decides to use it, it must inform the Quality Assurance Service. The latter, having compared the document in question with the rules imposed by the Regulation for use of the certification logo (Document R002), has ten days to complete the assessment and issue a judgment of conformity. If QAS has not provided any report within this period, the structure may consider the assessed document to be approved.

For each document or object containing the ITALCERT logo, the structure retains a copy available to the certification body.

(For operating details, see the "Use of ACCREDIA mark and ITALCERT logo" QAS/OPI.13.001 procedure).

## 8.4. Control of records

Records are documents that report data relating to the processes performed by structures adhering to the PQS and by the QAS itself. They allow for assessment of conformity with the requirements and the effective operation of the PQS. They may be either internal or external in origin and be on paper or IT media.

The "Documentation Management" procedure (QAS/MGP.07.054) contains indications in relation to management activities for quality records.

Politecnico di Milano General Management Staff Operation - Quality Assurance Service



The records are also kept with respect for the methods requested by the client (see, for example, financed activities).

Records are available from both the QAS and structures adhering to the PQS. Some records relating to general issues are stored by Central Administration, for example, for personnel management, they are stored at Human Resources and Organisation.

The methods described apply to the quality registration documents relating to suppliers and to client documents and data.

Records are documents that contain the results obtained or provide evidence of the activities performed. For each activity deemed critical, the required records are defined in the relevant procedures.

Politecnico ASICT (hardware and software) manages the University network and maintains the efficiency and security of the data and connection networks, as well as performing periodic backups of the general databases to safeguard data integrity. It is the responsibility of the individual structures to organise their archives and data to safeguard their integrity and plan the backups of locally managed computers/servers and measurement instruments/devices.

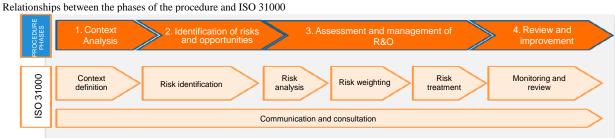
# 8.5. Actions to address risks and opportunities

In order to outline, implement and improve the Politecnico di Milano integrated Management System, the context variables have been analysed and considered (on the central level by the individual structures relating to the Politecnico Quality System and the Quality Assurance Service). classifying their relevant parts and requirements and preparing precise maps of the system's strategic risks.

The process of analysing the context, mapping, and listening to stakeholders is summarised in detail in the responsibilities and methods in the "Structure Document" produced by the Quality Assurance Service and on the local level in the "Structure Documents" of the individual structures adhering to the PQS.

The analysis of the context (locally and globally) is considered a true process whose objective is to determine the factors that influence the purposes, objectives and sustainability of the Politecnico di Milano Quality System.

To be able to define the perimeter of application of the Integrated Management System and the Management System of the individual structures adhering to the PQS, the relevant internal and external context variables and the stakeholders capable of influencing or being influenced by the activity, along with their needs and expectations, have been identified and are periodically reviewed.



Analysis and systematisation of the results leads to the identification of context factors that can be organised into three large dimensions (both internal and external):

- Social Dimension
- Environmental-physical Dimension
- **Economic Dimension**



The aspects indicated above can also be classified precisely into aspects of internal or external contexts. For example:

### **EXTERNAL**

- Policies and institutions
- Standards and regulations
- Technological innovations
- Environment and territory
- System of supplies
- Socio-economic system

#### **INTERNAL**

- Quality Policy
- Governance
- Organisational Structure, Processes, Services
- IT systems
- Customer relationships
- Human resources management
- Laboratories and instruments

These aspects, which could potentially affect the system, are determined and analysed in the individual "Structure Documents" through SWOT analysis (Strengths, Weaknesses, Opportunities, Threats), facilitating both the analysis of the context factors and the identification of associated risks (negative effects) and/or opportunities (potential positive effects).

After identifying the risks and strategic-operational opportunities within the PQS and all related structures, the analytical methodology allowed for priority, frequency and impact to be defined in such a way as to plan and carry out risk mitigation actions, consequently improving the Quality Management System. To identify the risks and opportunities and to assess the respective impacts, the structures adopt different approaches related to their activities and stakeholders:

- "influence on the requirements and expectations of clients" for those operating with contracts on behalf of third parties under ISO 9001;
- "influence and impact on regulatory aspects" for those operating in mandatory areas (CE marking, Testing Lab for Materials, Buildings and Civil Structures (LPMSC), etc.);
- "influence on the validity of the testing and calibration results" for those operating as a Testing/Calibration Laboratory under IOS/IEC 17025 accreditation.

The analysis is quantified based on the following drivers:

- frequency
- impact

The risk level is estimated using a quantitative approach, for example, the product  $R_{(risk)} = P \times D$  is calculated, where "P" indicates the probability of a given event occurring, according to the scale:

Probability level	Assigned value	
Unlikely	1	
Not very likely	2	
Likely	3	
Highly likely	4	

"D" indicates the level of damage caused by the event, according to the scale:

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Probability level	Assigned value
Mild	1
Modest	2
Significant	3
Serious	4



The risk level calculated thus is classified according to the following scale:

Risk level	Assigned value
Very low	R = 1
Low	2 < R < 3
Medium	4 < R < 8
High	$R \le 8$

	1	Risk (R)			
	High	4	8	12	16
(P)	Medium	3	6	9	12
Probability (P)	Low	2	4	6	8
Prot	Rare	1	2	3	4
		Low	Medium- Low	Medium- High	High
		Damage (D)			

By monitoring the indicator, it can be ascertained whether or not the risk is under control. If it is not, action plans and improvement strategies are implemented.

The results of this analysis and management procedure for risks and opportunities are periodically reviewed (at least once a year) in order to:

- Verify the up-to-date nature of the information and data used in the analysis phase
- Collect monitoring data on risk treatment actions and develop opportunities based on the specific indicators identified in the plan development phase
- Compare targets and results
- Define improvement and/or corrective interventions
- Plan the implementation of the interventions defined

## 8.6. Improvement

The laboratories and the whole of the Politecnico have adopted a method to assess the results based on continuously defined and monitored indicators and appropriate statistical analysis tools. A system has been established to manage non-conformities, setting out preventive actions and performing corrective actions when the results deviate from the targets. All this is detailed in the "PQS Management" (QAS/MGP.08.051) procedure.

The QAS and adhering structures have adopted methods to monitor and measure, where appropriate, the processes identified. In this circumstance, process indicators have been identified to demonstrate the capacity of the processes to achieve the planned results, limited to processes common to the adhering structures.

If the results are not achieved, the QAS and adhering structures adopt the appropriate corrections and corrective actions to guarantee the conformity of the service. The monitoring results are submitted annually to Management as input for the management review.

In view of the services it provides, each structure also defines appropriate instruments and methods to monitor and measure said services. Such activities are planned and documented. Each structure establishes the instruments (checklists, audits, interviews, etc.) it will use to monitor the services and which people with the necessary expertise and authority may monitor the services.

The monitoring results are submitted annually to Management as input for the management review (see Sect. 8.9 of this manual).



The specific indicators are defined on the level of the Management Review.

Customer feedback is managed by both the QAS and adhering structures. Such surveying is aimed at assessing opportunities to improve the services provided and the level of overall satisfaction of internal and external clients.

Customer satisfaction can be measured using different instruments:

- questionnaires;
- interviews:
- explicit communications of thanks for the services provided;
- final reports;
- focus groups;
- loyalty assessments;

The results of the investigation are submitted annually to Management as input for the management review.

In 2011, the University implemented a system to measure and assess the performance of its services, in which indices of user perception are used to evaluate the consistency between the quality of the services provided and user needs. Customer satisfaction is monitored annually by administering an online questionnaire to users via the University's web portal; the questionnaire is differentiated according to the type of user. Management shares and discusses the results at all levels and appropriate improvement activities are carried out.

#### 8.7. Corrective Actions

The responsibility for identifying and reporting situations that compromise the Quality System or the repetition of non-conformities to the Managers, the QAM or the QAS, is held entirely by personnel of the structures adhering to the PQS, in particular:

- during activities, checks and verifications;
- during internal audits;
- during the review of relationships and the resolutions of non-conformities as part of the management review;
- following customer reports (complaints, anomalies, non-conformities and requests for corrective/preventive actions);
- following a report from the control bodies (ACCREDIA, certification/inspection bodies, etc.).

The corrective actions (CA) are undertaken by the structure adhering to the PQS involved in the non-conforming actions identified and formalised in the NC, identifying the causes (which may be technical or managerial), timescale and person responsible, as well as verifying the timescales, methods and effectiveness.

The activities are defined and documented precisely in the Management of Findings procedure (QAS/MGP.07.055).

Within the defined timescales, the local QAM verifies the effectiveness of the CA in terms of eliminating the causes and objectively reducing the risk of not meeting the PQS requirements and/or concrete improvement of the system.

After the verification, the following may occur:

- the action is effective and the finding is closed;
- the action is ineffective for resolving the finding. Another analysis of the finding must be performed and further actions adopted, completing a new online form for managing the finding.
- sufficient evidence regarding the resolution or non-resolution the finding is not available when the effectiveness is verified. In this case, the local QAM proposes a new timescale.



If the finding arises during an internal audit, the process to manage the finding follows what is defined by the "Management of internal quality audits" procedure (QAS/MGP.94.003).

For a non-conformity, the laboratory must update, if necessary, the risk/opportunity analysis carried out in the planning phase, making it appropriately and adequately dynamic.

The evidence supporting the CA applied is managed through the Management of findings procedure (QAS/MGP.07.055).

#### 8.8. Internal audits

The methods described are extracted from the "Management of internal quality audits" procedure (QAS/MGP.94.003).

These activities guarantee the planned and formal performance of internal quality audits for the QAS and all structures adhering to the PQS. These audits are designed to assess the coherence and effectiveness of everything that is planned and implemented via the standards of reference, this Manual and, more generally, the management and operating procedures of the PQS.

In particular, the purpose of the audits is to determine:

- the compliance of what is implemented with the requirements of the PQS;
- the effectiveness of the PQS for implementing the Quality Policy expressed by the Rector;
- the implementation and effectiveness of the necessary corrective and/or preventive actions;
- the areas of potential improvement;
- any need for further audits in relation to the implementation and effectiveness of corrective actions.

The management of internal audits of the PQS is defined in the PQS documents, such as:

- Audit programme
- Management of internal quality audits (QAS/MGP.94.003);
- Management of audit findings (QAS/FOR.10.081);
- List of PQS qualified auditors;
- Model audit plan;
- Model audit report.

Second- and third-party inspection audits cannot replace internal technical and system audits.

The responsibility for planning and managing internal audits is held by the QAS, which performs them via qualified auditors either within or outside the QAS.

The auditors are independent from the audited structure, guaranteeing the objectivity and impartiality of the audit. The QAS personnel who also act as structure representatives may not perform audits of the structures they represent.

The auditors instructed to carry out the inspection will perform the audit activities after reading both the structure documentation, particularly the structure document, and the document of the individual structure prepared by the Quality Service, which summarises the main strengths and weaknesses of the individual structures adhering to the Politecnico Quality System. In this way, the audit will be carried out by performing a significant sample of the individual audited structures.

The University Quality Manager intervenes in performing audits only in exceptional cases where there are no other trained and qualified personnel able to perform the audit. The LAT Centre Manager and the LAB Centre Manager do not perform audits at accredited structures except in exceptional cases, in which case they are always accompanied by an independent AGM.

The same method is applied for audits carried out at structures outside the Politecnico as part of consultation provided by the QAS, with the sole exclusion, obviously, of assessing the application of procedures relating to the internal PQS.

The results of the internal quality audits are included in the Quality System review.



### 8.9. Management review

The management review, developed based on a previous assessment of the state of the Quality Structure, guarantees the Management's formal, planned and periodic assessment of the state of the PQS and its suitability for the requirements of the standards of reference in relation to the Quality Policy and any new objectives deriving from changes in internal conditions and the clients' explicit/implicit needs.

The review consists of the Management's verification of the implementation and effectiveness of the Quality System. It is performed at least once a year. The management review is prepared by the University Quality Manager with the Quality Service staff. Preparation of the review report also includes contributions from the individual reviews of all structures adhering to the PQS, including the QAS. The review report is verified and approved by the Quality Management Representative and the Rector's Delegate for Quality Assurance after defining the objectives and any proposals for improvement. A copy of the management review is sent to the Rector, the Director General, the LAT Centre Manager and the LAB Laboratory Manager. The document is also published on the portal.

The minimum elements to be assessed during the review are:

- Changes in internal and external factors;
- Final assessment with regard to meeting the previous year's targets, analysing the causes of any missing achievements;
- Definition of new targets;
- Results of internal and third-party audits;
- Non-conformities and recommendations for improvement;
- Status of corrective actions;
- Feedback from clients;
- Changes that may affect the Quality Management System;
- Adequacy of human resources, training and education of personnel;
- Data analysis, process indicators and monitoring results of the services.

For laboratories, the following may also be assessed:

- Reports from management and supervisory personnel;
- Inter-laboratory comparison or proficiency testing results.

The output elements from the review include, as a minimum:

- definition of new objectives for improvement;
- effectiveness of the management system and its processes;
- need for resources (technical, economic, personnel);
- need to review policies and assessments regarding the suitability of internal documentation.

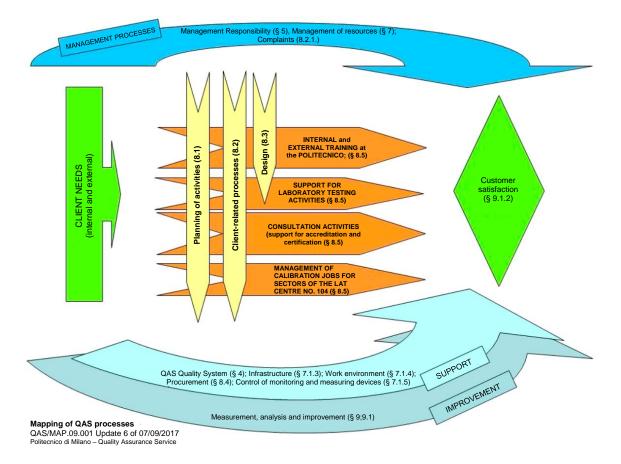
As output, the review highlights the assessments and decisions made to maintain and improve the Quality System: responsibility, need for resources, implementation timescales. The results of these actions form part of the basic information for subsequent management reviews, which will also consider the effectiveness of the actions taken. Extraordinary reviews are also planned following accreditation audits that trigger the need to take corrective action.

The process is defined and documented carefully in the "Management Review" procedure (QAS/MGP.07.053).

### 9. <u>Definition of processes in accordance with standard ISO 9001</u>

The processes are correlated differently depending on the scope of application of the different structures. The following diagram shows a map of the QAS processes:





The outline shows that all processes identified are closely correlated and integrated.

The ultimate aim common to all processes is customer satisfaction in the broadest sense of the term. For each of the processes identified, this Quality Manual describes the following aspects in a modular, simplified form:

- targets: process targets are indicated, describing the main aspects relating to the regulatory requirements that each process must meet;
- documentary correlations: indications refer to the University Regulations and other documentation in the Quality Management System (Management Procedures, Operating Procedures, Operating Instructions, internal system documents) necessary to fully describe the individual processes or parts thereof. The documents specify the precise aspects of each process, including, for example, a description of the process flow, the duties and responsibilities of the personnel involved, specification of any supporting documentation (forms, records, etc.), etc.;
- input: the possible input elements for the process are indicated<sup>1</sup>, i.e. resources, products, services, requirements, or output from other processes;
- process phases: the succession of characteristic activities of the individual process are reported, leaving the precise definition of the process model to the supporting documentation;
- output: the possible output elements from the process are indicated by way of example<sup>1</sup>, such as resources, products, services, requirements or input from other processes.

The attachments to the Manual contain maps of the processes carried out for the different structures based on the service offered. The annexes can be updated and augmented without affecting the revision index of the Manual itself. The annexes are listed in an index called Annex A.

<sup>&</sup>lt;sup>1</sup> The possible input and output listed may be present in each process in full or in part, depending on the precise characteristics of the process itself, as possibly specified in the supporting documentation.



Each Politecnico structure that outsources processes is directly responsible to the client and is required to supervise and check that the process entrusted externally is done professionally and in full respect of and in conformity with the established requirements and related legal and regulatory provisions.

Design, Development and Management of Jobs

#### 9.1. Design management

Design management guarantees the planned, controlled implementation of services provided by the structures adhering to the PQS. After several years of applying project design to the individual services, it has been seen that a good part of services provided by the QAS and adhering structures have been consolidated in both planning/design and implementation. It is therefore worthwhile to apply and develop such experience by designing and implementing services that are outlined carefully in the reference documents.

The design activity ensures that the results expected from the activity, process or anything else are expressed in terms of technical and/or managerial specifications (materials, products and processes), and are clearly understood, defined and achieved. The design may be carried out directly by the QAS with regard to its own activities (management of the PQS, training, consultation, accreditation and certification, etc.) or as coordinator of multidisciplinary activities carried out by several Politecnico structures. It may also be carried out directly by the individual structures adhering to the PQS in relation to their activities (tests, consultation, training, etc.).

The individual structures that carry out the design activities ensure that the definition of the aforementioned parameters allow the designed product or service to be realisable, verifiable and manageable under the expected operating or production conditions. Furthermore, to guarantee the successful outcome of the design activities, the structures undertake effective communication and updating among the different figures involved.

The process as a whole is defined and specified in PQS documents such as:

- "Design and development process" management procedure (QAS/MGP.07.050).
- "PIQ Design and development" form (QAS/MOD.07.055)
- Documentation management (QAS/MGP.07.054).

Input

Needs of the internal and/or external client, whether expressed or unexpressed.

Needs of the PQS and ACCREDIA (system innovation, technical innovations).

Specific needs relating to training activities,

which are illustrated in general elements such as:

Functional requirements.

Mandatory requirements.

Pre-existing elements (procedures, practices, human resources and materials,

etc.).

Process phases

Feasibility analysis or training needs.

Identification of the project manager and establishment of the working group. Preparation and review (approval) of the project: planning, definition of input

and output elements. Verification.

Pre-validation

Execution and/or provision

Post-validation

In the event of substantial changes to the input elements, phases c) to e) are

repeated



Output Design.

Product/service.

Specifications of service, provision and control for training and teaching

activities.

### 9.2. Management of training and orientation activities

The management of training and orientation activities guarantees the planned, controlled performance of the activities performed by structures adhering to the Politecnico Quality Management System, such as orientation upon entry, in the interim and upon leaving, Master's and specialisation courses (financed or not), lifelong learning, institutional training of Politecnico personnel and, in general, other specific courses organised by the structures themselves.

The activity as a whole is defined and formalised in the following University regulations, which are supplemented when necessary with specific instructions:

- Regulation of the Specialising Masters at the Politecnico di Milano;
- University Educational Rules;
- Regulation of lifelong learning courses at the Politecnico di Milano;
- Regulation of specialisation courses;
- Guidelines for managing training processes for Politecnico di

Milano personnel (document from Human Resources and Organisation)

The process as a whole is defined and specified in PQS documents such as:

- "Management of training activities" management procedure (QAS/MGP.02.016).
- "Management of orientation activities" management procedure (QAS/MGP.09.058).

•

<u>Input</u> Service specifications.

Delivery specifications. Control specifications.

Customer order.

Calls

Internal project

<u>Process phases</u> Advertising.

Preparation Conduct Controls

Final assessment

Output Achievement of training and orientation mission and goals

Self-financing

Funding

## 9.3. Management of experimental activities, testing and calibration

The management of experimental activities, tests and calibrations includes the entire procedure, from definition of the samples to delivery of the final results, in the form of the calibration certificate, calibration report, test report and final report.

As described in Chapter 5 of this manual, the activity begins upon receipt of the samples and is applied to all samples used for experimental checks and calibrations, from acceptance or sampling to the final return to the client or disposal. It ensures:

• a conformity check against the agreed requirements (defined in the offer and order phase, referring to standards and/or testing or calibration methods);



- unique identity coding;
- the definition, when necessary, of the sampling and sample-preparation methods;
- the protection of integrity, ensuring and monitoring when necessary the environmental conditions of storage and transportation methods, including the eventual segregation of samples found to be unsuitable in the conformity check;
- availability;
- confidentiality, when possible;
- return or storage of samples when requested and appropriate disposal of any waste.

The experimental activities, testing and calibration are organised and managed to guarantee that the individual operating structures adopt adequate, updated executive methods with respect to client needs and the requirements of the standards of reference, as well as their careful, documented use, ensuring that even minimal deviations are correct from the technical and scientific perspective, documented and agreed in advance with the client.

Such methods include maintenance activities and possible monitoring of suitable environmental conditions, controlled access to premises, sampling, handling, transportation, storage, use of equipment and software, documents of reference (technical standards, instruction manuals, data collection and processing forms, validation methods, etc.). The method and/or procedure also indicates the estimated measurement uncertainty and any statistical techniques and data processing involved. If the methods are developed internally or by external organisations that do not accept responsibility for their validation or they are standardised methods applied beyond the established scope of application, the Manager will guarantee their internal validation.

<u>Input</u> Order.

Incoming Sample(s). Agreed requirements.

Process phases Possible sampling.

Acceptance checks;

Granting of assignments;

Execution;

Quality control of results

Collection and processing of data.

Result.

Conformity of result to the method.

Formalisation.

Check and approval.

Sending to client.

Any amendment or re-issuance.

Archiving.

Return to client or disposal.

Output Data,

Traceability,

Report, calibration certificate, calibration report or test report.

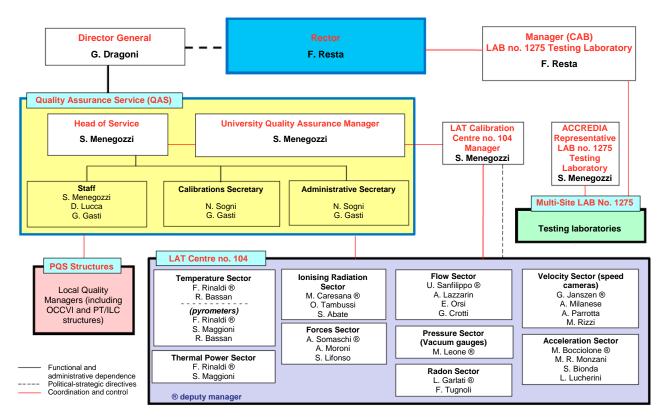


### 9.4. ANNEXES

Annex 1	Organisation Chart of Quality Assurance Service
Annex 2	List of structures adhering to PQS, UNI EN ISO 9001 certified
Annex 3	List of structures adhering to PQS and with ministerial or regional recognition
Annex 4	List of structures adhering to PQS and UNI EN ISO/IEC 17025 accreditations
Annex 5	List of structures adhering to PQS
Annex 6	Map of processes relating to training activities and special projects for university teaching
Annex 7	Map of processes relating to testing and calibration laboratories
Annex 8	Map of processes relating to orientation
Annex 9	Organisation Chart of the Mechanical Engineering Laboratory - Department of Mechanical Engineering
Annex 10	Organisation Chart of the Transport Safety Laboratory - Department of Aerospace Science and Technology – DSTA/LAST
Annex 11	Organisation Chart of the Microstructural Analysis of Materials Service – SAMM - "G. Natta" Department of Chemistry, Materials and Chemical Engineering
Annex 12	Organisation Chart of the Testing Lab for Materials, Buildings and Civil Structures - Research Support Services Area
Annex 13	Organisation Chart of the ReLAB Laboratory – Renewable heating and cooling LAB – Energy Department
Annex 14	Organisation Chart of the TextilesHUB Laboratory
Annex 15	Organisation Chart of the Certification Body for the Certification of Property Assessors
Annex 16	DCMC Organisation Chart
Annex 17	Radiation Metrology Laboratory



### ANNEX 1 - Organisation Chart of Quality Assurance Service



Director General Graziano Dragoni /signature/

Organisation chart QAS/DOC.00.003, Update 32 of 01/04/2021

Page 1 of 1



# 9.5. ANNEX 2 - List of structures adhering to PQS, UNI EN ISO 9001 certified

Adhering Structure	Accredited Structure	Scope of application		Site
Central Administration - Research Support Services Area  Wind Tunnel Laboratory		Management of the Wind Tunnel as part of experimental activities of testing and research	Х	Bovisa
Department of Chemistry, Materials and Engineering	Polymer Testing Laboratory	Testing activities for characterisation of polymer materials	X	Leonardo
Department of Aerospace Science and Technology		Training activities and special projects for university teaching	X	Bovisa
		Vibration dampers	X	
		Measurement of inertia characteristics of a rigid body using the Intensino	X	
		Calibration of chains for force measurement	X	
		Calibration of geometric masters via CMM	X	
Department of Mechanical Engineering		Calibration of measurement circuits in strain gauge applications	X	Bovisa
		Scale calibration	X	
		Calibration of pressure measurement systems	X	
		Calibration of contact measurement systems from pantographs to catenaries	X	
		Calibration of laser triangulation sensors	X	
Energy Department	Fluid Dynamics of Machines Laboratory (LFM)	Experimental activities on air safety valves	X	p- '
		Training activities and special projects for university teaching	X	Bovisa



# 9.6. ANNEX 3 - List of structures adhering to PQS and with Ministerial or Regional Recognition

The Politecnico is recognised as a binding certification body.

In particular, the Testing Lab for Materials, Buildings and Civil Structures (LPMSC or LPM)\* is authorised (Notified Body no. 1777) in accordance with Regulation (EU) 305/2011 as a:

Product certification body (issuance of constancy of performance certificates) for

- structural bearings (EN 1337-3:2005; 1337-5:2005 and 1337-7:2004)
- spherical and cylindrical bearings with special sliding materials (EAD 050004-00-0301, EAD 050009-00-0301, EAD 050013-00-0301)
- anti-seismic devices (EN 15129:2009)
- pre-tensioning systems to pre-stress structures (so-called post tension devices PT) (EAD 160004-00-0301 formerly ETAG 013)

Factory production control certification body for hot-rolled steel products for industrial uses (EN 10025-1:2005).

Finally, the LPMSC operates as an Official Laboratory in accordance with Article 20 of Law 5 November 1971 no. 1086, "Standard for the regulation of works in cement conglomerate, normal and pre-stressed and with a metal structure", and Article 59 of Presidential Decree 6 June 2001 no. 380 "Laboratories" for the certification of tests on construction materials.

European authorisation of the Energy Department (Thermometric Research Laboratory)\*\*, as Notified Body in accordance with Directive 89/106/EC awaiting notification in accordance with Regulation (EU) no. 305/2011 as a Testing Laboratory for System 3 certification in compliance with harmonised standard EN 442-1 for requirements 3, 4, 6".

<sup>\*</sup> The Ministerial Notification will expire on 19 June 2021 and will be issued again on the Ministerial level. Once this period has elapsed, the laboratory will transition to the Accredia Testing Department within 18 months.

<sup>\*\*</sup> The Ministerial Notification will expire on 26 June 2021 and the renewal will be made with Accredia Testing Department.



# 10.8 ANNEX 4 - List of structures adhering to PQS and UNI EN ISO/IEC 17025 Accreditations

Adhering Structure	Accredited Structure	Scope of application	ACCREDIA DT	ACCREDIA DP	Site
		Assessment to test the effects of exposure to severe environmental conditions on fastening systems for railway tracks. UNI EN 13146- 6:2012; BS EN 13146-6:2012; EN 13146-6:2012		Х	
		Determination of the tensile characteristics of fibre-reinforced composite materials with cement matrix - AC 434 2018 - ICC		X	
		Determination of the tensile characteristics of fibre-reinforced composite materials with cement matrix LPMSC/POP/FRCM. 03.001		Х	
Central Administration	Testing Lab for Materials, Buildings and Civil Structures	Determination of the tensile characteristics of composite materials with a polymer matrix (1–90 kN) LPM/POP.03.001 Update 10 of 02.09.2019, EN 2561:1995, UNI EN ISO 527-5:2009, ASTM D3039/D3039M-17 (excluding § 7.4, § 7.5, note 5, § 10.1, § 10.2, § 11.1, note 8, § 11.4)		х	
- Research, Innovation and Business Relations Area	(LPMSC)	Corrosion test in artificial atmospheres - salt spray test with NSS method (neutral salt spray) EN ISO 9227:2017 NSS method (neutral salt spray) § 5.2.2		Х	Leonardo
		Static, dynamic and fatigue tests on prestressed monobloc railway sleepers. RFI TCAR SF AR 03 002 F, part III (excluding § III.I; III.2.1, III.2.3.2, III.2.4.2, III.2.5, III.3.1, III.3.3, III.3.6) + § IV.1; EN 13230- 2:2016 (excluding § 4.2.2, 4.3.2.2, 4.4.2.3, 4.5.3, 4.5.4, 4.5.5, 4.6, 5)		Х	
		Concrete constructions with under sleeper pads (USP): USP pull-out resistance tests and effects of severe environmental conditions. RFI TCAR SF AR 03 008 A, part III (§ III.3.2, III.3.3); BS EN 1542:1999 (§ 5, 7); EN 1542:1999 (§ 5, 7)		Х	
	Forces Sector	Calibration of metal material testing machines - concrete material testing machines - testing equipment for force measurement	Х		
Department of Chemistry, Materials and Engineering	Microstructural Analysis of Materials Service (SAMM)	Quantitative determination of concentrations of airborne asbestos fibres in indoor environments - Scanning electron microscopy. DM 06/09/1994 SO GU no. 288 10/12/94 Annex 2 Section B		X	Leonardo
Department of Aerospace Science and Technology  Department of Mechanical Engineering	LaST (Laboratory for the Safety of Transport)	Tests to verify the conformity of competition car seats Standard 8855- 1999 - FIA		X	Bovisa
	Velocity Sector	Calibration of measuring devices for instantaneous vehicle speed (speed cameras)	X		201104
		Fatigue resistance on full-scale axles EN 13261:2009+ A1:2010 (annex H + § 3.2.3 excluding cut-out samples)  Determination of attenuation of impact loads. BS EN 13146-3:2012; EN 13146-3:2012		Х	Bovisa
		Determination of clamping force to the rail. BS EN 13146-7:2019; EN 13146-7:2019			



	Determination of electrical resistance of	DT	DP	
	mounted fastening systems. UNI EN 13146-5:2012; EN 13146-5:2012			
	Determination of torsion resistance. BS EN 13146-2:2012; EN 13146-2:2012			
	Determination of stiffness. UNI EN 13146-9:2011 (§6.1, 6.2, 7.1, 7.2 ) + RFI			
	TCAR SF AR O5 010 C (§III.3); EN			
	7.2 ); BS EN 13146- 9:2009+A1:2011			
	(§6.1, 6.2, 7.1, 7.2)  Determination of longitudinal rail			
	restraint. EN 13146-1:2019; BS EN 13146-1:2019			
	Pull-out resistance test. BS EN 13146-			
	Performance requirements for fastening			
	(§III.3 excluding §III.3.1); BS EN			
	5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-			
	2:2012+A1 (§§ 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11)			
	Metal sleepers for Armament 60E1 manoeuvring systems. RFI DTCSI SF			
	AR 03 002 1 A (\$III.2.3, III.2.4, III.2.5, III.2.6, III.2.7, III.3) + EN 13146-9:2020			
	(§, 7.1, 7.2) + RFI DTCSI SF AR 05 004		X	
	); BS EN 13146-9:2020 (§ 7.1, 7.2 )			
	UIC RFI TCAR SP AR 03 001 B			
	III.3) + EN 13146- 9:2020 (§, 7.1, 7.2) +			
	RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146- 9:2020 (§ 7.1, 7.2 ); BS EN			
	13146- 9:2020 (§ 7.1, 7.2 )  Measurement of the friction coefficient			
	between pantograph contact strips and contact wire of overhead line and			
	measurement of wear rate for contact			
	DMA-IM.LA\ST TE65 of 2004			
	3452-1:2013/E.C. 2014			
	components. UNI EN 13749:2011 (E)			
	Static tests on bogie frames and			
	components. UNI EN 13749:2011 (E) §6.2.3 + Annex F			
	Static, dynamic and fatigue tests on prestressed monobloc railway sleepers.			
	RFI TCAR SF AR 03 002 F, part III (\$III.2: III.3. IV.1) + UNI EN 13146-			
	5:2012; EN 13230- 2:2016 (E)			
	Static, dynamic and fatigue tests on			
	crossings. RFI TCAR SF AR 03 003 E,			
	13146-5:2012; EN 13230-4:2016 (E)			
	Static and dynamic tests on twin-block			
	reinforced sleepers. EN 13230-3:2016 (E) (excluding §§ 4.4.3,4.4.4, 4.4.5,			
_		13146-9:2009+A1:2011 (§6.1, 6.2, 7.1, 7.2); BS EN 13146-9:2009+A1:2011 (§6.1, 6.2, 7.1, 7.2)  Determination of longitudinal rail restraint. EN 13146-1:2019; BS EN 13146-1:2019  Effect of repeated loading. EN 13146-4:2020; BS EN 13146-4:2020 Pull-out resistance test. BS EN 13146-10:2017; EN 13146-10:2017 (E)  Performance requirements for fastening systems. RFI DTCSI SF AR 05 004 1 A (§III.3 excluding §III.3.1); BS EN 13481-2:2012+A1:2017 (§§ 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§§ 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11)  Metal sleepers for Armament 60E1 manoeuvring systems. RFI DTCSI SF AR 03 002 1 A (§III.2.4, III.2.5, III.2.6, III.2.7, III.3) + EN 13146-9:2020 (§7.1, 7.2); BS EN 13146-9:2020 (§7.1, 7.2); BS EN 13146-9:2020 (§7.1, 7.2)  Hollow metal sleepers for armament 60 UIC RFI TCAR SP AR 03 001 B (§III.2.2, III.2.3, III.2.4, III.2.5, III.2.6, III.3) + EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 I A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 I A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 I A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 I A (§III.3); EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 I A (§III.3); EN 13 445-9:	13146-9:2009+A1:2011 (§6.1, 6.2, 7.1, 7.2 ); BS EN 13146-9:2009+A1:2011 (§6.1, 6.2, 7.1, 7.2 )   Determination of longitudinal rail restraint. EN 13146-1:2019; BS EN 13146-1:2019     Effect of repeated loading. EN 13146-4:2020     Pull-out resistance test. BS EN 13146-10:2017; EN 13146-10:2017 (E)     Performance requirements for fastening systems. RFI DTCSI SF AR 05 004 1 A (§III.3 excluding §III.3.1); BS EN 13481-2:2012+A1:2017 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012+A1 (§8 5.1,5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 1346-9:2020 (§7.1, 7.2); BS EN 13146-9:2020 (§7.1, 7.2); BS EN 13146-9:2020 (§7.1, 7.2) + RFI DTCSI SF AR 05 004 1 A (§III.3); EN 13146-9:2020 (§7.1, 7.2); EN 13230-12011 (E) (§6.2.4 + Annex G	13146-9:2009-A1:2011 (§6.1, 6.2, 7.1, 7.2); BS EN 13146-9:2009+A1:2011 (§6.1, 6.2, 7.1, 7.2)     Determination of longitudinal rail restraint. EN 13146-1:2019; BS EN 13146-1:2019     Effect of repeated loading. EN 13146-4:2020     Pull-out resistance test. BS EN 13146-4:2020     Pull-out resistance test. BS EN 13146-10:2017; EN 13146-10:2017 (E)     Performance requirements for fastening systems. RFI DTCS1 SF AR 05 004 1 A (§III.3 excluding §III.3.1); BS EN 13441-2:2012-A1(2017 (§§ 5.1.5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11); EN 13481-2:2012-A1(3§ 5.1.5.2, 5.3, 5.4, 5.5, 5.6, 5.10, 5.11)     Metal sleepers for Armament 60EI manocuvring systems. RFI DTCSI SF AR 03 002 1 A (§III.2.3, III.2.4, III.2.5, III.2.6, III.2.7, III.2.5, III.2.4, III.2.5, III.2.6, III.3.7, III.3.



Adhering Structure	Accredited Structure	Scope of application	ACCREDIA DT	ACCREDIA DP	Site
		Aerodynamic loads of trains on open track: 1- Cross-wind effects on	<i>D</i> 1	<i>D</i> 1	
		passengers on platforms and workers at the lineside; 2 - Head pressure pulse;			
		Pressure loads in open air TSI HS			
		LOCPAS 2014, Regulation (EU) no.			
		1302/2014 (§§ 4.2.6.2.1,4.2.6.2.2 + Appendix J-1, index 108, EN 14067-			
		4:2013 §§ 4.2.2.1, 4.2.2.2, 4.2.2.3 e			
		4.2.2.4 + Appendix J-1, index 109, EN			
		14067- 4:2013 §§ 4.1.2 + 6.2.3.13, Appendix J-1, index 94, EN 14067-			
		4:2013 §§ 6.2.2.1, 4.2.4 and table 7 +			
		ISO 8756: 1994+ 6.2.3.14, Appendix J-1, index 95, EN 14067-4:2013 §§ 6.1.2.1,		X	
		6.1.2.4, 6.1.2.2, 4.1.4 and table 4 + ISO			
		8756: 1994) + Recommendation no.			
		ERA-REC-120-2015/REC  Maximum pressure variations in tunnels.			
		Regulation (EU) no. 1302/2014 (§§			
		4.2.6.2.3 + 6.2.3.15 + Appendix J-1, Index 96, EN 14067- 5:2006 +A1:2010,			
		\$ 4.2.2)			
		Penetrant liquid inspection. UNI EN ISO 3452-1:2013/E.C. 2014			
	Acceleration Sector	Calibration of accelerometer chains, single-sided transducers	X		
Department of Physics	Low Pressure Sector	Calibration of pressure transducers - vacuum gauges	X		Como
Department of Civil and Environmental Engineering	Flow Sector	Calibration of water volume flow meters	X		Leonardo
Engineering		Calibration of dosimeters for radiation			
		protection, radio-diagnostics and high			
		dose quantities - Dosimeters for environmental radiation protection X-			
	Ionising Radiation Sector	rays and dosimeters for radiation	X		
	Sector	protection - Dosimeters for environmental gamma radiation			
		protection - Dosimeters for personal			
		radiation protection			
	Heating Bodies Sector	Calibration of sample heat exchangers  Calibration of noble metal	X		
		thermocouples - base metal			
		thermocouples - resistance thermometers			
		- Thermometric chains (temperature indicators and transmitters) with noble			
		metal thermocouples - Thermometric	X		
	Temperature Sector	chains (temperature indicators and transmitters) with base metal			
Energy Department		thermocouples - Thermometric chains			Bovisa
Energy Department		(indicators and temperature transmitters)			Bovisa
		with resistance thermometers Temperature measurements in industrial			
		steam generators	X		
		Calibration of active instruments to measure the concentration of radon in the			
	Radon	air - Passive devices to measure the	X		
		concentration of radon in the air			
		integrated over time  Tests and evaluation of thermal			
		performance at full and partial loads and			
		calculation of the nominal and seasonal performance indices (GUE and SGUE) /			
	Dalak	Water side enthalpy test method in		v	
	ReLab	heating mode and cooling mode		X	
		0–100kW BS EN 12309-1:2014+BS EN 12309-3:2014+BS EN 12309-			
		4:2014+BS EN 12309-5:2014+BS EN			
		12309-3:2014+BS EN 12309-			



Adhering Structure	Accredited Structure	Scope of application	ACCREDIA DT	ACCREDIA DP	Site
		Tests and evaluation of annual thermal energy ratio and annual gas use efficiency of absorption heat pumps / Simplified calculation method (0–100 kW)			
		VDI 4650 Blatt 2/Part 2 :2013  Tests for determining sound power level			
		(20 Hz – 10 kHz) BS EN 12102-2:2019			
		Tests, performance rating and requirements for marking of domestic hot water units (0–30 kW) BS EN 16147: 2017 with the exclusion of withdrawal cycles: 3XL and 4XL (Attachment A - Table A.3), BS EN 16147:2017 except load profiles: 3XL and 4XL (Attachment A - Table A.3)			
		Thermal tests and performance rating (COP and EER)/ Water side enthalpy test method in heating and cooling mode (0–100 kW) BS EN 14511-1:2018+BS EN 14511-2:2018 with the exclusion of 'medium temperature' and 'low temperature' conditions of Table 25 +BS			
		EN 14511-3:2018+BS EN 14511-4:2018 Tests for measuring airborne noise and determining sound power level (20 Hz – 10 kHz) BS EN 12102-1: 2017			
		Tests for determining sound power level and sound energy levels - Comparison method for hard-walled test rooms BS EN ISO 3743-1:2010			
		Thermal tests and performance rating at part loads and calculation of seasonal performance index (SEER and SCOP) / Water side enthalpy test method in heating mode, cooling mode (0–100 kW) BS EN 14825: 2018 with the exclusion of DX-to-water (brine) heat pumps and the 'medium temperature' and 'low temperature' conditions in Table 16 and Table 17		X	
		Tests for determining sound power level (20 Hz – 10 kHz) BS EN 16583:2015  Tests for determining performance (0–100 kW) BS EN 1397:2015 except Sections: 6.1, 6.2, 6.2.1, 6.2.2, 6.3, 6.4, 6.5 and 6.6., BS EN 1397:2015 except Sections: 6.1, 6.2, 6.2.1, 6.2.2, 6.3, 6.4, 6.5 and 6.6.			
		Determination of tensile properties of plastics. Part 3: Test conditions for films and sheets and Part 1: general principles (0–50 kN) ISO 527- 3:2018 + ISO 527-1:2012			Leonardo
Intenden		Biaxial tensile test for technical textiles (0–25 kN; 0–50 kN) MSAJ/M-02-1995 Biaxial tensile test for technical textiles (0–25 kN; 0–50 kN). BS EN 17117-12019			
Interdepartmental laboratory	TextilesHUB	1:2018, UNI EN 17117-1:2019 Test for determining maximum force and elongation at maximum tensile strength, using the strip method (0–50 kN). UNI EN ISO 13934-1:2013 (part 1: strip method test) + ISO 13934- 1:2013 Test for determining the maximum force		X	
		Test for determining the maximum force and elongation at maximum tensile strength, using a strip method (0–50 kN). UNI EN ISO 1421:2017 (Method 1: strip method test), ISO 1421:2016			



Adhering Structure	Accredited Structure	Scope of application	ACCREDIA DT	ACCREDIA DP	Site
"Giulio Natta" Department of Chemistry, Materials and Chemical Engineering	DCMC Laboratory	Determination of mass concentration of dust (= 0.01 mg) UNI EN 13284-1:2017 par. 8.2-8.3-8.4-8.6  Determination of the massive concentration of ammonia with the IC technique (= 0.02 mg/L) ISO 21877:2019 Annex D (detailed analytical method present in ISO 14911:1999)  Determination of hydrogen sulphide (H2S) in gaseous effluents with the IC technique (= 0.005 mg/L) UNI 11574:2015 par. 9		X	Leonardo



# 10.9 ANNEX 5 - List of structures adhering to PQS

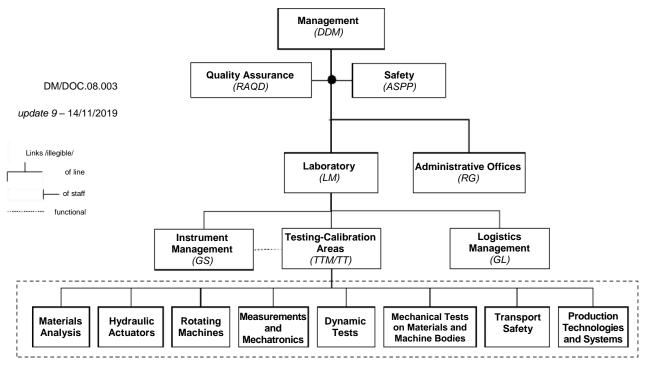
Adhering Structure	Accredited Structure	Scope of application	PQS	Site	
Central Administration - Research Support Services Area	Testing Lab for Materials, Buildings and Civil Structures (LPMSC)	The Testing Lab for Materials, Buildings and Civil Structures is authorised (Notified Body no. 1777) in accordance with Regulation (EU) 305/2011 as a: Product certification body (issuance of constancy of performance certificates) for:  * structural bearings (EN 1337-3:2005; 1337-5:2005 and 1337-7:2004)  * spherical and cylindrical bearings with special sliding materials (EAD 050004-00-0301, EAD 050009-00-0301, EAD 0500013-00-0301)  * anti-seismic devices (EN 15129:2009)  * pre-tensioning systems to pre-stress structures (so-called post tension devices – PT) (EAD 160004-00-0301 – formerly ETAG 013) Factory production control certification body for hotrolled steel products for industrial uses (EN 10025-1:2005).	X	Leonardo	
		It operates as an Official Laboratory in accordance with Article 20 of Law 5 November 1971 no. 1086, "Standard for the regulation of works in cement conglomerate, normal and pre-stressed and with a metal structure", and Article 59 of Presidential Decree 6 June 2001 no. 380 "Laboratories" for the certification of tests on construction materials	Х		
Department of Chemistry, Materials and Engineering	Microstructural Analysis of Materials Service (SAMM)	Measurement of coating thicknesses - optical microscopy	X	Leonardo	
Department of Mechanical Engineering		Certified calculation SEM Calibration Calibration of thermometers Calibration of data acquisition systems	X X X X	Bovisa	
Department of Electronics, Information and Bioengineering	Electrical Measurements Sector	Calibration in direct and alternating voltage, direct and alternating current, resistance	X	Leonardo	
Energy Department	Thermotechnical Research Measurements Laboratory (MRT)	Notified body in accordance with Directive 89/106/EC awaiting notification in accordance with Regulation (EU) no. 305/2011 as a Testing Laboratory for System 3 certification in compliance with harmonised standard EN 442-1 for requirements 3, 4, 6".	Х	Bovisa	



# 10.10 ANNEX 9 – Organisation Chart of the Mechanical Engineering Department

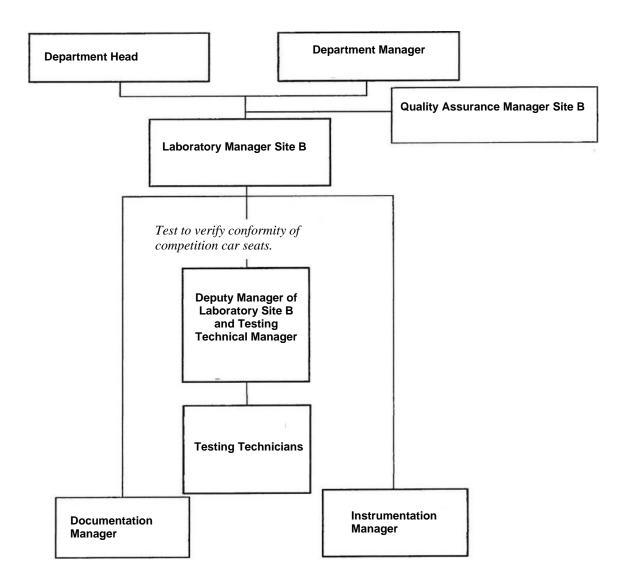
Organisation Chart of the Mechanical Engineering Laboratory - Department of Mechanical Engineering

### **Functional Organisation**





10.11 ANNEX 10 – Organisation Chart of the Transport Safety Laboratory - Department of Aerospace Science and Technology – DSTA/LAST



DSTA/LAST/DOC.14.001 update 7 of 2019.08.09



10.12 ANNEX 11 - Organisation Chart of the Microstructural Analysis of Materials Service – SAMM - "G. Natta" Department of Chemistry, Materials and Chemical Engineering

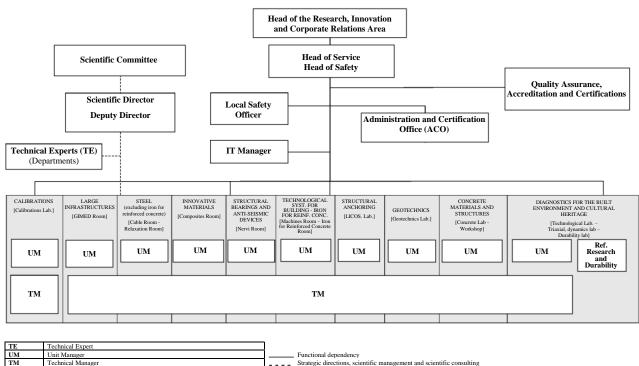
**Quality Assurance Manager Laboratory Manager LM** QAM M. F. Brunella M. F. Brunella **Testing Manager TM for electronic** microscopy (\*deputy LM for the DM test 06/09/1994 SO GU no. 288 10/12/94 Annex 2, section B) **Testing Manager TM for sample** preparation, optical microscopy, laser profilometry, X-ray diffraction P. I. Mattia Ronchi

The Department of Chemistry, to which the SAMM laboratory belongs, is not organised through a departmental Quality Management System. All activities regarding the Quality Management System are managed directly between the SAMM Laboratory and the Quality Assurance Service.

CMIC/SAMM.DOC.02.002 Update 6 of 15/02/2018



### 10.13 ANNEX 12 - Organisation Chart of the Testing Lab for Materials, Buildings and Civil Structures - Research Support Services Area

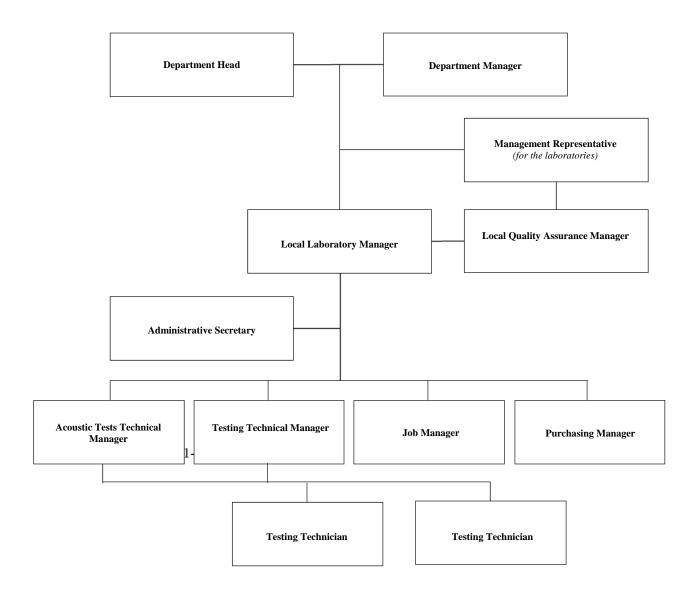


Unit Manager
Technical Manager
Quality Assurance Manager Quality Assurance Assistant

DM/DOC.08.006 update 12 – 14/11/2019

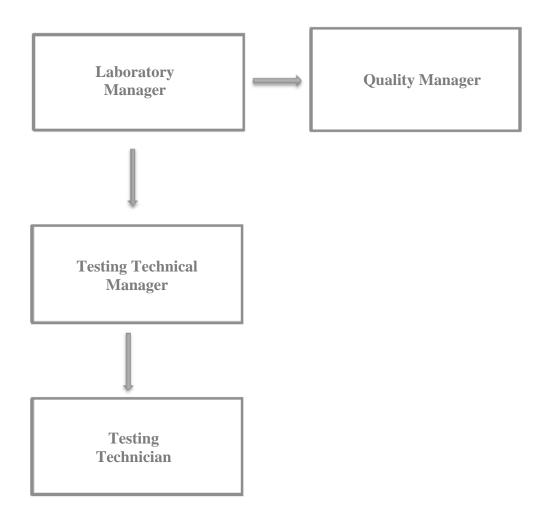


# 10.14 ANNEX 13 - Organisation Chart of ReLAB Laboratory





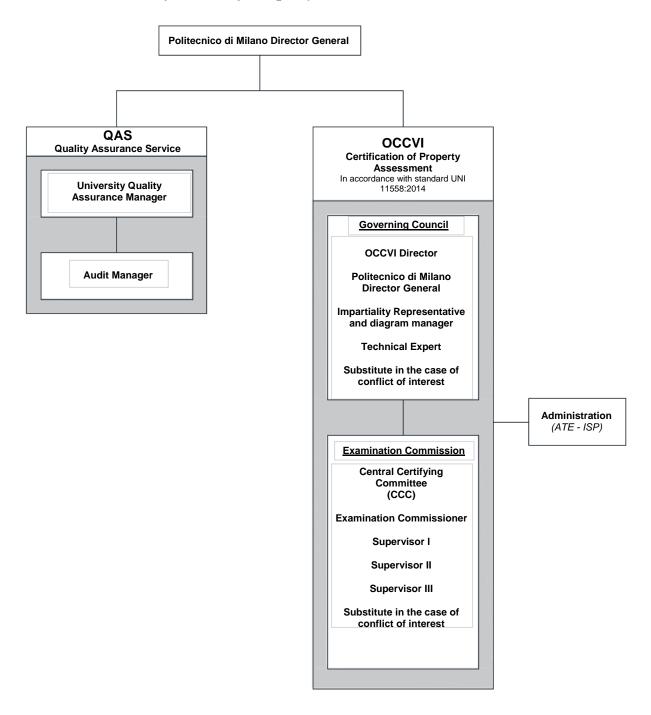
### 10.15 ANNEX 14 - Organisation Chart of Textiles HUB Laboratory



TH.DOC.17.001 of 31.5.2017



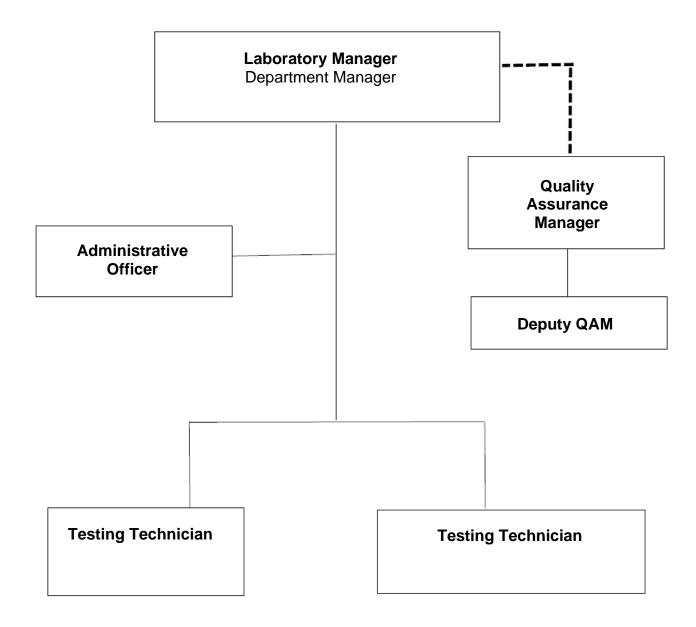
# 10.16 ANNEX 15 - Organisation Chart of Certification Body for the Certification of Property Assessors



VI\_ORG.02 of 21.02.2020 rev. 02



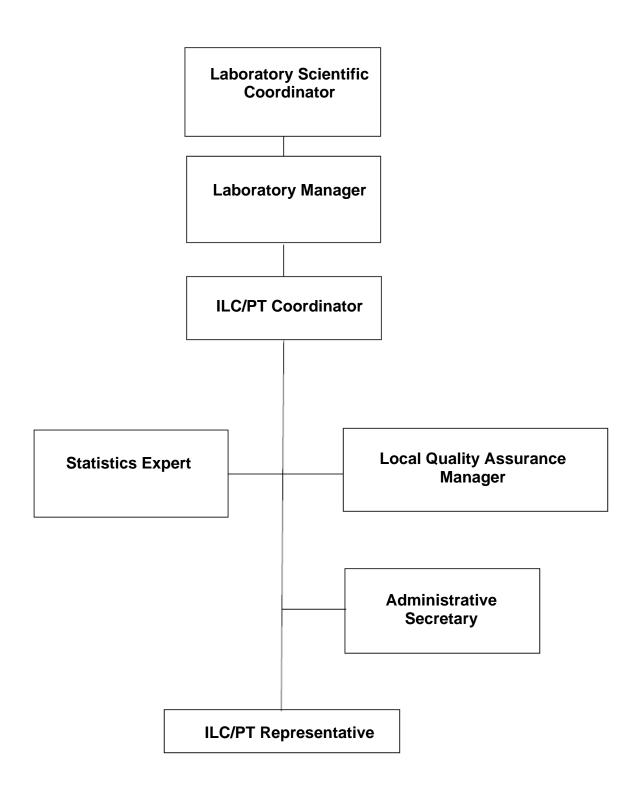
### 10.17 ANNEX 16 - DCMC Laboratory



DCMC/DOC.20.001 update 0 of 10/07/2020



### 10.18 ANNEX 17 - Radiation Metrology Laboratory



LMR/DOC.21.002 - update 0 of 2021-03-15