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QUALITY MANUAL (PROPOSED)


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1 Política de Calidad

Elaborated by Director Angels Sahuquillo – Nov/2009

La **política de calidad** de Mat Control es proporcionar un buen servicio que satisfaga las necesidades de los clientes y de los usuarios, y mantener una relación mutuamente beneficiosa con los colaboradores y suministradores, sin la cual la continuidad del laboratorio quedaría comprometida.

Con la finalidad de satisfacer estos objetivos, se han puesto en marcha de forma simultánea varias estrategias:


- Proporcionar materiales para el control de calidad (QCM) que satisfagan las necesidades de clientes y usuarios
- Diseñar esquemas de ensayos de aptitud adecuados para satisfacer los objetivos y necesidades de los laboratorios participantes de acuerdo a los requisitos establecidos por la guía ISO para proveedores de ejercicios interlaboratorio.
- Diseñar una organización preparada para cubrir las necesidades de un entorno cambiante
- Mantener a los colaboradores y suministradores de Mat Control informados de sus actividades generales, y especialmente de aquellas que se deriven de su relación con el laboratorio

Los compromisos de **la Dirección se compromete son:**

- Asegurar que el nivel de equipamiento y recursos materiales es adecuado a las actividades que se desarrollan, llevar a cabo las acciones necesarias para seguir el desarrollo de la tecnología en este campo, y para conseguir los recursos necesarios para implementarla.
- Asegurar un nivel de capacidad técnica en perfecta adecuación con las necesidades del laboratorio, potenciando y mejorando los conocimientos de los que dispone el personal.
- Llevar a cabo todas las acciones necesarias para mantener una estructura y recursos humanos tales que permitan alcanzar los objetivos de calidad.
- Promover actividades que faciliten la información con los colaboradores y suministradores.
- Asegurar el compromiso del personal para proporcionar la satisfacción de las expectativas de los clientes mediante los estudios de viabilidad, el desarrollo de nuevos productos, y ofreciendo servicios de calidad competitivos.
- Promover la mejora continua de la organización y del sistema de calidad

Para alcanzar los objetivos se implementa un sistema de calidad basado em ISO/IEC 17043.

El Sistema de Calidad de Mat Control está a disposición de todo el personal y es un compromiso de la Dirección que cualquier usuario antes de utilizar las instalaciones conozca dicho sistema.

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1.1 Quality Policy – Free translation

The quality policy of Mat Control is providing good service to meet customer needs and users, and maintain a mutually beneficial relationship with partners and suppliers, without which the continuity of the laboratory would be compromised. In order to meet these objectives, we have implemented several strategies simultaneously:


- Provide materials for quality control (QCM) that meet the needs of customers and users.
- Develop proficiency testing schemes appropriate to meet the goals and needs of the participating laboratories according to the requirements of the ISO guide for providers of interlaboratory exercises.
- Creating an organization prepared to meet the needs of a changing environment.
- Keeping partners and suppliers informed about general Control Mat activities, especially those arising from their relationship with the laboratory

The commitments of the Director are:

- Ensure that level of equipment and material resources is appropriate to their developing activities, implement actions necessary to follow the development of technology in this field and to secure necessary resources to implement it.
- Ensure a level of technical capacity in perfect harmony with the needs of the laboratory, enhancing and improving the skills of staff.
- Undertake all actions necessary to maintain such structure and human resources to achieve quality objectives.
- Promote efforts to provide information with partners and suppliers.
- Ensure staff commitment to provide the satisfaction of customer expectations through feasibility studies, development of new products, offering competitive services with quality.
- Promote continuous improvement of the organization and quality system.

To achieve the goals it is implementing a quality system based in ISO/IEC 17043.

The Control Mat Quality System is available to all staff and there is a direction commitment to assure that any user will know such system before using installations.

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2 Laboratory Description

The “Laboratorio de Preparación de Materiales para el Control de la Calidad” - **Mat Control**- have as basic objectives prepare environmental and agro-food items to quality control, organize regular patterns of proficiency tests and advise on subjects related to quality assurance of the analytical laboratories.

Mat Control was established in June 2001 by the research group QÜESTRAM (*Qualitat en l'especiació d'elements traça i radionúclids en el medi*) of Department of Analytical Chemistry, University of Barcelona and recognized by the Government of Catalunya (SER2009-1188). The group had experience since early 90 in activities related with quality assessment.

At the end of the year 2001, Mat Control project obtained the financial support of *Centre d' Innovació y Desenvolupament Empresarial (CIDEM) de Generalitat de Catalunya*. This funding allowed the consolidation of the laboratory activities in environmental field for preparation of Quality Control Material (QCM) and organisation of first proficiency test (PT) campaigns.

From 2003 to nowadays Mat Control is organising regular PT schemes (around 30) in environmental and agro-food fields and also had produced more than 125 different QMCs. As proficiency testing schemes (PTS) is a useful tool for laboratories that are accredited or in the process of obtaining accreditation, according to ISO norm 17025, the number of participant laboratories increase in each campaign.

Fundación Bosch i Gimpera (FBG) of University of Barcelona Group support Mat Control in management of financial issue.

Location

Mat Control is allocated in Faculty of Chemistry of University of Barcelona in address:

Departament de Química Analítica

Facultat de Química.

Universitat de Barcelona

Av. Diagonal, 647

08028 Barcelona


Telf.(34) 93 4037274

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E-mail: Mat Control@ub.edu

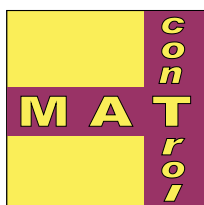
Website: <http://www.ub.es/dqa/matcontrol>

The juristic liability of Mat Control is University of Barcelona, Gran Via Les Corts Catalanes, 585, postal code 08007, Barcelona-Spain.

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Since 19th May 2003, Mat Control is a registered Spanish trademark (N° 2.514.411) by the Spanish Patent and Trademark Office in class 42 (scientific research and industrial service), including the Mat Control design (logo).

Logotype:



2.1 Organization

Following organization chart (Figure 1) shows the organization of University of Barcelona and current Mat Control context.

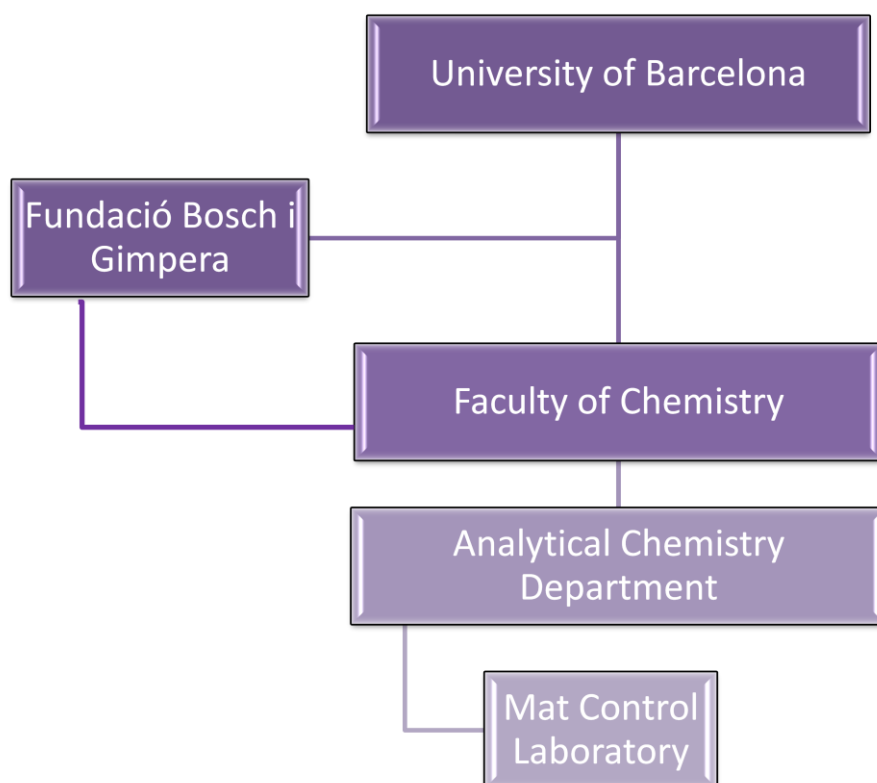



Figure 1 – Organization chart of Mat Control

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2.2 Activities

Figure 2 shows all processes that can be involved in Mat Control activities. These processes are dividing in three types, being strategic development, key process and support.

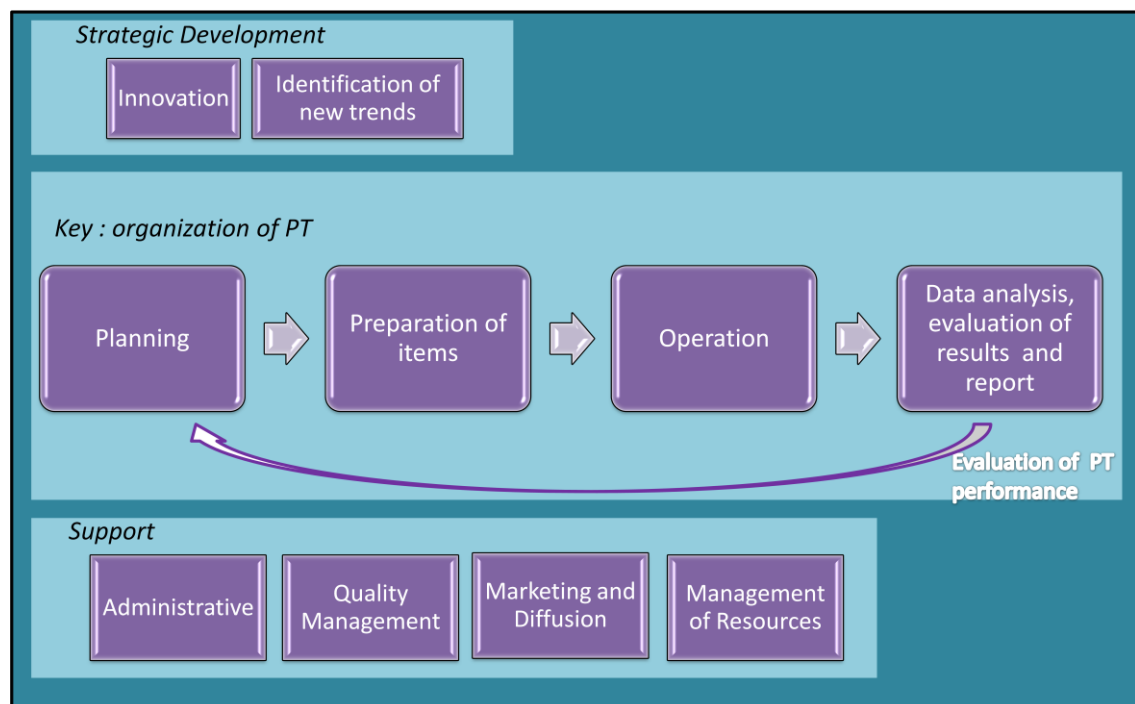



Figure 2 – Mat Control activities

Strategic development processes are responsible to keep Mat Control growing and increasing the portfolio of assistance. These contemplate activities as research about new material, feasibility studies, identification of potential participants, identification of inter comparison laboratories needs.

Key processes contemplate the organization of PT in many aspects, since the PT request until reporting results to participants. These processes are divided in four main areas (Planning, Preparations of items, Operation and Data analyses, evaluation of results and report) that reach technical requirement items 4.4 to 4.9 on ISO/IEC 17043.

Support processes allow Mat Control organize PTs with quality assurance, adequate for the market and equilibrate in financial and human resources. Administrative activities well executed are the key to Mat Control perform the PT schedule and obtain customer satisfaction.

Complying with improvement policy, all processes are cover by continuous evaluation of performance.

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3 Personnel

Figure 3 shows personnel organization chart. Mat Control is aware about conflict of interests when decided all positions in the hierarchy.

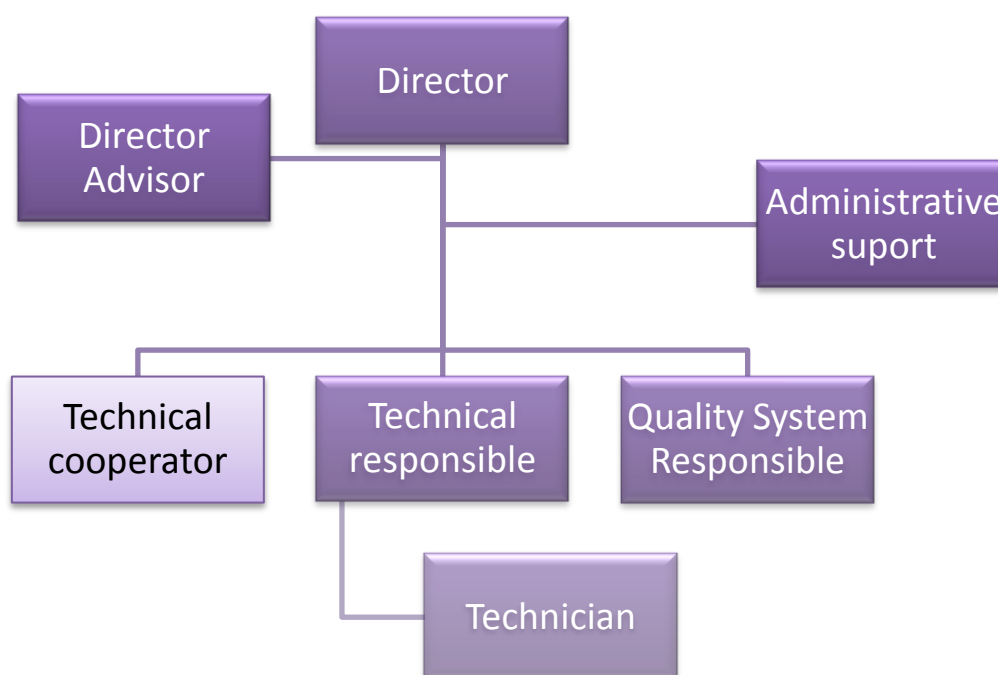


Figure 3 – Personnel organization chart

Being a quality management principle, involvement of people is very important to Mat Control quality system. Everyone should feel important and responsible for the quality system operation. All abilities shall be used with the improvement proposal.


Due to the dimension of Mat Control, it is necessary for some members to execute more than one activity in the quality system structure.

During the annual management review, following [PGC/MAT/003](#) “Review of quality system” direction, identify training needs and establish a plan for each staff member involved with development of a proficiency testing scheme.

3.1 Tasks and responsibilities

3.1.1 Director

- Conduct Mat Control.
- Define organization and management structure.

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- Identify the responsibilities of key personnel in the proficiency test activities, avoiding potential conflicts of interest.
- Work, together director advisor, in a strategic way to obtain resources and develop Mat Control.
- Quality management
 - Establish together with director advisor the Quality Policy and actions to attend it.
 - Approve the Quality Manual
 - Establish contact with accreditation body.
 - Review and approve documents elaborated by quality system responsible.
- Management financial.
 - Review and approve purchasing.
 - Conduct all commercial activities.
- Design PTS
 - Review and approve documents elaborated by technical responsible.
 - Plan of the proficiency test scheme, together technical staff and expert, included the preparation of items.
 - Operated PTS, together technical staff and expert, tasks that involved instruction to participants, distribution of items and data analyses.
 - Authorize the final report PTS.
 - Define together with technical staff and expert, training needs for all personnel.

3.1.2 Director Advisor

- Establish together with director the Quality Policy and actions to attend it.
- Work, together director, in a strategic way to obtain resources and develop Mat Control.
- Responsible for improvement of the management system.
- Review and approve all quality management documents.
- Plan and organize audits as required by the schedule.
- Define together director and technical, training needs for all personnel.

3.1.3 Technical responsible: staff or expert

In Mat Control the technical responsible is classified as “staff” or “expert” according to the link with the institution. **Staff** have a work contract with University of Barcelona or FBG and **Expert** are recognized

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by University of Barcelona as linked directly with Mat Control due to their knowledge in a specific subject.

Tasks for both figures are the same:

- Elaborate and document procedures and instructions necessary to assure the quality of all aspects of proficiency testing as purchase, reception, and storage of reagents, proficiency test items, reference materials, and other consumable materials.
- Plan of the proficiency test scheme, together director, included the preparation of items. Establish methods and work schedules for PTS.
- Operated PTS, together director, tasks that involved instruction to participants, distribution of items and data analyses.
- Take decisions about PT items suitability (homogeneity and stability). Establish statistical design for analysis.
- Conduct commercial activities, included up date website.
- Inspect or otherwise verify if purchased items complying with standard specifications or requirements.
- Plan technician activities to assure good performance in PTS.
- Inform to director about material and equipments needs.
- Demonstrate experience and technical competence of subcontractors.
- Clarify customers' requests, check customer's feedback and solve of complaints reasons.
- Identify, inform and solve technical nonconformities.
- Review and approve of requests, tenders and contracts.
- Responsible for the evaluation of performance of PTS.

3.1.4 Quality System Responsible

- Organize meetings with personnel to evaluate and to review the management system.
- Evaluate, together with technical, suppliers of critical supplies and services which affect the quality of proficiency testing schemes.
- Responsible for implementation, maintenance and improvement of the management system.
- Elaborate, identify and codify all quality management documents
- Establish document control policies and procedure.
- Control documents.
- Participate in evaluation of performance of PTS.

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3.1.5 Technical co-operator

Technical cooperator is someone working eventually in Mat Control. As Mat Control is part of university group, some students can do research projects and carry out some activities that comply with management system of the laboratory. These activities can be the same of quality system responsible, technical responsible and/or technician and are supervised by director.

3.1.6 Technician

- Support the proficiency test developing chemical analyses involved.
- Prepare, characterize, handling, packing and labelling of PTS items.
- Do maintenance, verification and/or calibration of equipments and materials.
- Control stock of material. Inform to technical about reagents and equipments needs.
- Control environmental conditions and maintenance of installations that could have influence on the proficiency test activities.

3.1.7 Replacement

In case of absent of any worker, the replacement of his/her activities is done according Table 1, always respecting training and abilities context.

Table 1 -Function replacement


Function	Replacement by
Director	Director advisor or Technical responsible
Director advisor	Director or Technical responsible
Quality system responsible	Technical responsible
Technical responsible	Another technical responsible or director
Technician	Technical responsible

3.2 Personnel profile

For each job description there are minimum requirements of knowledge, experience and type of link with the institution. Mat Control files evidence that all personnel are able to develop designed activities.

Director:

- Work contract with University of Barcelona
- PhD in Chemistry (preferably) or in Scientific field.
- Experience in reference material production and proficiency test organization.

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Director Advisor:

- Work contract with University of Barcelona or recognition as expert.
- PhD in Chemistry (preferably) or in Scientific field.
- Experience in Quality System.
- Experience in research group management.

Technical expert:

- Recognized by University of Barcelona as linked with Mat Control.
- Degree in Chemistry or Scientific field.
- Experience in reference material production and proficiency test organization.

Technical staff:

- Work contract with University of Barcelona or FBG
- Degree in Chemistry.

Quality System responsible:

- Work contract with University of Barcelona
- Degree in Chemistry.
- (Recommended) experience or specific formation in quality management.


Technical cooperador:

- Linked by project with University of Barcelona
- Degree or current graduation in Chemistry.

Technician:

- Work contract with University of Barcelona or FBG
- Technical formation (*ciclo formativo de grado superior*) with focus in laboratory analyses and environmental control.

Mat Control considerate knowledge and experience to contract personnel. In some cases the candidate must pass a qualification process. These requirements and processes description are described in [PGC/MAT/004](#) "Management of Personnel". This document also deals with basic and continuous training.

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4 Confidentiality

The identity of participants in a proficiency testing scheme is confidential and known only to persons involved in the operation of the proficiency testing scheme unless the participant waives confidentiality. All information supplied by a participant to Mat Control is treated as confidential.

To assure that all personnel have knowledge about the confidentiality policy, everyone that have access to such information signed um confidentiality term (in PGC/MAT/004) before start the activities. This agreement requires the employee to protect “confidential information” and trade secrets. In this agreement, “Confidential Information” includes scientific, engineering and technical know-how, processes, related documentation owned or marketed by Mat Control or its clients, marketing strategies, customer requirements and customer lists.

5 Management quality system

The quality management system approach allows Mat Control work according customer requirements. For this, Mat Control quality system covers explanation of organization, definition of personnel tasks and profile, management of activities and all documents necessary to develop the work. Seeking satisfaction of proficiency test´s customers, the quality system is structured to attend technical and management requirements of ISO/IEC DIS 17043.


Annex 1 shows the equivalence between this Quality Manual items and ISO/IEC DIS 17043.

5.1 Structure and control of documents

The documentation in Mat Control is structured aiming cover all points that can influence in the quality of proficiency test scheme. The propose is elaboration of documents that allow all personnel to work in the same way, following quality system principles, registering all evidences and such evidences are traceable.

Mat Control has the document structure based in five types of documents, being Quality Manual (Manual de Calidad - MC), General Quality Procedure (Procedimientos General de Calidad – PGC), Standardized Operation Procedure (Procedimientos Normalizados de Trabajo - PNT), Registers and External Documents.

Quality Manual (MC) covers all explanation about Mat Control and is the main document which is possible following all other documents. Standardized Operation Procedures (PNT) establish details that

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basement Mat Control activities and General Quality Procedures (PGC) cover all activities in a way to assure the quality. Figure 4 illustrates this documents interaction.

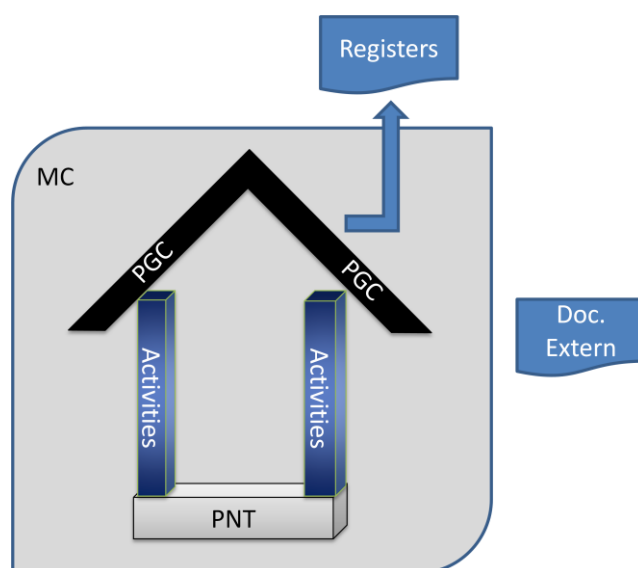


Figure 4 – Documents interaction

The elaboration and changes of PNT and PGC is done according [PGC/MAT/002](#) “Writing, review, approval, distribution and maintenance of procedures”. The code of procedures is generated according [PGC/MAT/001](#) “Codification and structure of procedures” and have as objective to facilitate the identification and recognizing easily the document propose.

Registers are generated during Mat Control activities and kept as evidences. External documents are not elaborated by Mat Control but influence in activities and quality, being also management by the quality system.

Table 2 brings personnel responsibilities to management each type of document and also the periodical review. Having continual improvement as a principle, all personnel can suggest procedures modification that are analyzed by the superior and/or director.


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Table 2 – Responsible of elaboration and control of documents

Document	Writing	Review	Approval	Control of Copy	Periodical Review
MQ	Quality system responsible	All personnel can review and suggest modifications	Director	Quality system responsible	3 years
PGC	Quality system responsible	All personnel can review and suggest modifications	Director	Quality system responsible	3 years
PNT	Technical responsible, Quality system responsible, Technician	All personnel can review and suggest modifications	Director	Quality system responsible	3 years
Registers	All personnel	All personnel can review and suggest modifications	Technical responsible, Quality system responsible, Director	Technical responsible, Quality system responsible	-----
External	-----	-----	Technical responsible, Director	Quality system responsible	-----

5.2 Review of request, tenders and contracts

Mat Control has the police to do well detail the description of the PT and [PNT/MAT/006](#) “Communication with participants” assures that all important information is release. After receive de PT information (see 6.2.3) clients decide if the PT exercise is technically appropriate for them, thus Mat Control do not review request, tenders and contracts. Any change in previous PT agreement is report to participants as soon as possible, for them decide if the modifications can influence their proposal in the PT.

As a service to customers, Mat control organize meeting in the end of the campaign to give feedback and review customers’ needs.

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5.3 *Subcontracting services and purchasing*

Suggestion of document:

- [PGC/MAT/005](#) - “Evaluation of technical competence and quality of services and material”.

5.4 *Incidents*

Suggestion of document:

- [PGC/MAT/006](#) - “Detection, management of incidents and improvement”.

5.5 *Internal audits and Management reviews*

Suggestion of document:

[PGC/MAT/003](#) “Review of quality system”

6 **Technical Requirements**

6.1 *Infrastructure*


The infrastructure allows Mat Control to work according safety principles and analytical quality.

Mat Control follows ISO/IEC 17025 principles, being competent in the measurement of the properties that is analyzing in each proficiency test. When it is necessary accredited laboratory is subcontract to chemical tests. The production and handling of PT items are done according ISO Guide 34 principles. These principles touch many areas as sampling, management equipments, selection of methods, traceability, accommodation and environmental, method validation.

6.1.1 **Accommodation and environmental**

Mat Control occupied an area of about 70 m² divided into areas of pre-treatment, homogenization and packaging, general store, prepared items of PT store and office. It is built to current safety standards and participated in emergency plan of the Faculty of Chemistry. All units incorporate fire detector system, fire extinguishers, emergency showers and eye wash devices. In addition, the local has suction system to remove solid particles of atmosphere, mainly used during PT items preparation.

All activities in Mat Control can be developed in room temperature because this factor is not a considerate critical to the quality of PT and is not controlled. To provide more comfortable work condition

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and also to avoid equipments work in extremes temperatures, the local has air conditioning that can be use according needs.

Faculty of Chemistry allocated Mat Control in the basement in rooms 05A, 05B, 05C, 008 and 010. For the some technical, commercial and administrative activities, Mat Control is supported by others installations of analytical chemistry department in the third floor of the Faculty.

The access to Mat Control installations is restricting to laboratory staff and research group members. The access of external people is supervised by Mat Control staff. In both cases, the access is authorized by Director.

6.1.2 Equipment

Equipments used to confirm the content, homogeneity and stability of PT testing items are appropriately validated and maintained. Mat Control assure quality of management equipments with [PNT/MAT/001](#) “Management of equipments”. This documents deals with identification, maintenance, calibration, verification and operation procedures for all equipments.

6.2 Key processes


Key processes contemplate the organization of PT in many aspects, since the PT request until reporting results to participants and final evaluation of all steps involved in the PT. These processes are divided in four main areas, as showed in Figure 2 (pg 8).

- Planning
- Preparations of items
- Operation
- Data analyses, evaluation of results and report

In the end of exercise, Mat Control does an evaluation of performance (metaevaluation) to verify how all steps were carried out. This evaluation is included in the annual [PGC/MAT/003](#) “Review of quality system” to support the improvement of the system.

6.2.1 Planning of proficiency testing schemes

Mat Control plans those processes which directly affect the quality of the proficiency testing scheme according [PNT/MAT/002](#) “Planning proficiency test scheme”. After the meeting with organized committee to establish the aims of the exercise, Mat Control takes decision for the PT scheme as:

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- Define nature and amount of samples
- Define analytical methods
- Define range of parameters
- Define statistical design
- Define assigned value method
- Define personnel involved
- Plan item preparation
- Plan homogeneity and stability test
- Plan contact with participants (information and way to participant send results)
- Plan distribution of items
- Plan evaluation of results
- Plan report results

Annex C of [PNT/MAT/002](#) “Planning proficiency test scheme” allows Mat Control builds a chronogram for the exercise. This schedule is Mat Control tool to run well the proficiency test and take decisions in the right time for each activity.


6.2.2 Preparation of proficiency testing items

[PNT/MAT/003](#) “Preparation of proficiency test items” and [PNT/MAT/004](#) “Homogeneity and stability tests” are the documents that support Mat Control in the preparation activities.

The production and handling of PT items are done according ISO Guide 34 principles. After prepared, items are storage in a separated room, segregate from chemical substances and other materials or environmental conditions that can cause contamination or degradation, from the time of preparation to their distribution to participants.

During the storage, some items are analyzed to test the stability of the lot and before any exercise items are also analyzed to ensure that Mat Control distributes items according the plan and objectives of PT.

When it is necessary disposal items, Mat Control following the rules of Faculty of Chemistry to identify and collect residues.

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6.2.3 Operation of proficiency testing schemes

In Mat Control the operation of proficiency testing scheme is management for two main documents: [PNT/MAT/005](#) “Labelling, packing and distributions of PT items” and [PNT/MAT/006](#) “Communication with participants”.

Communication with participants is done according previous agreement between parts (e.g. mail, email, fax, etc) and have some principles:

- **Confidentiality:** Technical responsible and director are responsible for all transferring information and they are aware about any risk that can affect confidentiality police.
- **Open channel:** Clients can contact MATCONTROL anytime to solve questions and to complain.
- **PT objectives:** Any change in previous PT agreement is report to participants as soon as possible, for them decide if the modifications can influence their proposal in the PT.


Generally Mat Control contact clients in five situations:

- **Inform about PT:** Give details of the scope, analytical methods, fees for participation, documented eligibility criteria for participation, confidentiality arrangements, and how to apply.
- **Inform about samples:** Sent together samples. Give participants code, confirm content in the box, details of analytical methods and “received sheet” that shall be filling and return by participants.
- **Excel sheet reporting results:** Allow participants send results information in a standardize way.
- **Report of results:** Inform statistical analyses and performance of individual participants.
- **Call for final meeting:** Invitations to participants meet and discuss results, complain and solve doubts about PT.

6.2.4 Data analysis, evaluation of proficiency testing scheme results and report

Results sent for participants are analyzed statistically according [PNT/MAT/007](#) “Data analysis and evaluation of proficiency testing scheme results”.

Proficiency test reports shall be clear and comprehensive. In Mat Control reports are done according [PNT/MAT/008](#) “Elaboration of reports”. This document brings the minimum information that a report should have. All reports are verified for the technical responsible before be send to clients.

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7 Annexes

7.1 Annex A - Equivalence between Quality Manual items and ISO/IEC DIS 17043.

ISO/IEC 17043	MATCONTROL Quality manual
4.1	6.1.
4.2	3
4.3	6.1.1 / 6.1.2
4.4	
4.4.1	6.2.1
4.4.2	6.2.2
4.4.3	6.2.2
4.4.4	6.2.1
4.4.5	6.2.1 / 6.2.4
4.5	6.2.1
4.6	6.2.3
4.7	
4.7.1	6.2.4
4.7.2	6.2
4.8	6.2.4
4.9	6.2.3
4.10	4
5.1	2.1
5.2	5
5.3	5.1
5.4	5.2
5.5	5.3
5.6	5.3
5.7	5.2
5.8	5.4
5.9	5.4
5.10	5.4 / 5.5
5.11	5.4
5.12	5.5
5.13	5.1
5.14	5.5
5.15	5.5