

	Facultat de Química Departament Química Analítica MATCONTROL	PGC/MAT/002/01
		Writing, review, approval, distribution and maintenance of procedures
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**Title:** Writing, review, approval, distribution and maintenance of procedures

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## 1 Objective

Establish the main steps to writing, review, approval, distribution and maintenance of procedures.

## 2 Scope

This rules as apply for all technical or quality management procedures elaborates by Mat Control.

## 3 Definitions

**Controlled copy** is a copy of a procedure that is sent to a recipient. It is identified with the number of copies and distribution site. Printed in red "DO NOT COPY" on all pages.

**Distribution place** is a numeric code to identify the physical place where the controlled copy is. This code corresponds to door number of the laboratory or office where the document is.

## 4 Related Procedures

PGQ/MAT/001/01 - Codification and structure of procedures.

## 5 Responsibilities

### Director of Mat Control

- Approve all procedures or indicate a person to do it.

### Quality system responsible

- Write General Quality Procedures (PGC)
- Write Standardized Operating Procedures (PNT) or delegate it to another person.
- Review PNTs or delegate it to another person.
- Assign code for all procedure.
- Copy, control and distribute copies of the procedures.
- Communicate removal of documents.
- Remove and destroy copies obsolete.
- Make and evaluate change proposal for PGC
- Program and run total review of PGC in each three years.
- Keep update electronic files of procedure.

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### Technical responsible

- Review General Quality Procedures (PGC)
- Write Standardized Operating Procedures (PNT) or delegate it to another person.
- Review Standardized Operating Procedures (PNT) written by another person or delegate it to another person.
- Make and evaluate change proposal for PNT
- Ask controlled copies and keep them in a traceable location.
- Program and run total review of PNT in each three years.
- Keep update electronic files of procedure
- Assure that staff reading of documents related to the activities undertaken.

### Technician

- Write Standardized Operating Procedures (PNT)
- Read all documentation delivered by technical or quality.
- Keep controlled copies in a traceable location.
- Co-operate in total review of PNT in each three years.
- Communicate incidents in the procedures (deterioration, errors ,...).
- Communicate improvement proposals.

## 6 References

Not applicable.

## 7 Instructions

### 7.1 Writing, review and approval

#### General Quality Procedures (PGC)

These procedures will be drafted and reviewed by the Quality System Responsible. In some cases may be reviewed and signed by a technical responsible. The Quality System Responsible evaluate and make

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change proposals, when agree with changes shall sign and dated the document. If applicable, return to the director who should sign and dated.

Once completed the review procedure, it shall be approved by director of Mat Control. If (s)he agrees, shall sign and dated. Otherwise, shall return to the editor with the proposed changes, and restarted the process.

### **Standardized Operating Procedures (PNT)**

A PNT can be writing by any member of Mat Control or for a research group member that is related with activity or process in focus on PNT.

The person who writes a PNT shall do according structure indicated in PGQ/MAT/001/01. Once drafted, the PNT is undertaking to review.

Once completed the review procedure, responsible for drafting send an electronic copy of the document to quality system responsible, who will review the format and coding assigned by following the PGQ/MAT/001/01.

Finally, the document will be signed and dated by the persons responsible for drafting and revision it, and approved by quality system responsible and director.

## **7.2 Distribution**

### Controlled copies

Once drafted, reviewed and approved a procedure, the quality system responsible do the controlled copies required. (see Application Form and send copies • controlled procedures).

In case the document replaces a previous version, this should be noted in the first page with date of substitution, and take controlled copies.

Assigned to each copy of manuscript, number of copy controlled and the appropriate distribution place, as well as in red print: "DO NOT COPY" on all pages and appendices.

In the case of proceedings containing graphs, diagrams or other relevant information in color, the color of "DO NOT COPY" will be gray.

Controlled copies of a procedure is given together with a receipt called "Distribution of controlled copies" (see Annex A), which will be signed by the person addressed and record by quality system responsible.

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### Order and Send of controlled copies.

To request single copies of procedures, staff will ask the quality system responsible by form "Request of controlled copies " (see Annex B).

## **7.3 Maintenance**

### Location of controlled copies

In each work area will meet those procedures (general and specific) that could affect the activities carried out therein, and be available to all staff working there. Only the version in force in will be in circulation.

Any change in the layout of installations is communicated to quality system responsible to update your computer file and change the cover of the controlled copy.

### Update procedures

All procedures must be reviewed every three years from the date of entry into force of the document that corresponds to the date of the adoption or replacement if necessary.


The quality system responsible shall notify the persons responsible for the three-year review using the form "Review Procedures" (see Annex C), for procedures that will expire within three months. This form should be returned to quality system responsible.

- If the contents of the procedure was not changed, the deadline is extended by three years until a new review.
- If the procedure has been changed, it shall have accompanied with the release form filled out.
- If the procedure is considered obsolete, the person making the review attached controlled copies together form.

### Withdrawal of controlled copies of procedures

If a procedure is replaced by a new version, when this is done to reach the distribution site responsible for the quality system responsible shall withdraw and destroy all copies of version controlled replaced.

If a proceeding is dismissed, the quality system responsible will inform the Mat Control distribution sites affected indicating the reasons shall be its withdrawal and destruction.

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### Changing procedures

The modification of a procedure can be proposed by any member of the laboratory using the form "Proposed Changes" (see Annex D). Corrections will not be taken on the controlled copy, since this is the document in force until the publication of a new version.

The proposed amendments can be considered significant (miscalculation, a change in the procedure section,) or not significant (not significant typographical errors, misspellings ...). When the amendment is deemed significant, or when they propose a minimum of 5 non-significant changes, it shall review the document and editing a new version.

The assessment of the modification is carried out by technical responsible or quality system responsible.

### Archive procedures

The quality system responsible is responsible filed procedures and forms of distribution of controlled copies, proposed changes, request of controlled copies and review procedures. Also, keep a computer file of all procedures.

When the procedure is no longer in force, it will cancel the computer file and the original copy will overprinted with the historical record, the first page, "Obsolete Document", which will remain a minimum of 5 years before its destruction.

## **7.4 Annex A- Distribution of controlled copies – in elaboration**

## **7.5 Annex B - Request of controlled copies - in elaboration**

## **7.6 Annex C - Review Procedures - in elaboration**

## **7.7 Annex D - Proposed Changes" - in elaboration**