



# Procedure

## Facility Maintenance

### AUTHOR

Quality Assurance Assistant	Signature.....
-----------------------------	----------------

### VERIFICATION

Quality Assurance Manager	Signature .....
---------------------------	-----------------

### AUTHORIZATION

Quality Assurance Manager	Signature ..... Date 22.04.2013
---------------------------	------------------------------------

**Expiry Date      22/04/2015**



## Re-Approvals Form

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_

REAPPROVED ON \_\_\_\_\_  
EXPIRES ON \_\_\_\_\_  
QUALITY ASSURANCE \_\_\_\_\_



## 0. Revision Matrix

REVISION	DATE	UPDATE CARRIED OUT AND REASON FOR UPDATE
01		Date Rev. 00 Withdrawn
02		Date Rev. 01 Withdrawn
03		Date Rev. 02 Withdrawn
04		Date Rev. 03 Withdrawn
05		Date Rev. 04 Withdrawn
06		Date Rev. 05 Withdrawn
07		Date Rev. 06 Withdrawn
08		Date Rev. 07 Withdrawn
09		Date Rev. 08 Withdrawn



## 1. Scope and Application

To define the method of communicating, carrying out and evaluating maintenance operations in the facility.

## 2. Responsibility

Any function is required to communicate any anomaly to the Department Manager (or the Assistant in his absence) who then informs the Process Engineer.

Each manager (or the assistant in his absence) along with the Process Engineer is responsible for the supervision and approval of the work performed.

## 3. Procedure

All the maintenance interventions carried out in the facility are reported in MN.SOP.001 "Maintenance Plan"

### 3.1 Incidental Maintenance

Whenever a fault or failure is identified, communicate this directly to the Department Manager (or the Assistant in his absence), who transfers the maintenance request to the Process Engineer by completing and signing the maintenance record form (P.SOP.010/All.01) indicating the applicant, the date and time of request, a detailed description of the work to be performed and if this is urgent or standard.

The Process Engineer has the task of assessing the extent of the problem and establish the possibility of termination thereof with an intervention using internal company resources or an external contractor, indicating in this case the name of the contractor.

In the case of hazardous work (e.g. work at a height, heat, confined spaces, etc..) the Process Engineer is required to specify the type of danger and communicate this to Safety personnel to assess the working procedure to be followed.

In the case of work related to the environment, the Process Engineer is required to communicate this to Environment Personnel to assess the working procedure to be followed.

In each case the process engineer signs and dates the maintenance record form.

The Process Engineer or the maintenance operator, defines along with the Manager or Assistant of the department concerned, the time and manner of the maintenance work, reporting a description of the operation to be carried out on the maintenance record form and delivering a copy of this form to the department concerned.

The Department Manager or Assistant, signs the maintenance record form for acknowledgment and approval of the work.

The Maintenance operator, responsible for carrying out the work reported in the form, records the date and time when the intervention commenced and when it was concluded, a description of the intervention carried out and the outcome produced.



Once the operation is concluded, the Process Engineer verifies the work carried out with the help of the Department Manager or Assistant, signing and dating the maintenance record sheet for approval. Quality Assurance sign and stamp the maintenance record sheet and issue a "Maintenance Verification Form" (P.SOP.010/All.05) to verify that the maintenance has been performed in compliance with GMP.

All Maintenance record sheets, both internal and external, are stored by the process engineer for ten years.

### 3.2 Programmed Maintenance

The Process Engineer provides for the programmed maintenance according to the deadlines set out in the appropriate "Maintenance Program" MN.SOP.002. All annual maintenance has a tolerance of 30 working days to execute the maintenance operations.

For all other maintenance, programmed with a frequency of less than one year, a tolerance of 15 working days is permitted.

The Process Engineer proceeds as described in section 3.1.

In general, the following rules apply:

- Depending on the production schedule, in the case of a production downtime of more than one month, the Process Engineer suspends maintenance operations.
- In the event of a halt in production of more than one month, prior to resuming production, the facility must be serviced and subsequent cleaned.

Periodically, following each maintenance intervention, Quality Assurance prepare the "Maintenance Verification Form" (P.SOP.010/All.05) to certify that all maintenance audited was implemented in compliance with GMP and proper operating conditions have been restored following the maintenance intervention.

The module contains:

- the type of maintenance scheduled / incidental;
- Maintenance intervals: monthly, bimonthly, tri-monthly, quarterly, half-yearly, annual, biannual, five-yearly, ten-yearly, unplanned;
- the judgment: approved / rejected;
- notes.

Quality Assurance affix the date and signature for verification.

The Process Engineer is responsible for updating the maintenance program.

If the deadline for maintenance completion is not fulfilled for justified reasons, regarded as such by Quality Assurance, open a deviation in accordance with procedure G.SOP.018, indicating the reason in G.SOP.018/All.01.

The Process Engineer must insert the new date in the maintenance program.

### 3.3 Maintenance Operations

The label "Maintenance in progress" (P.SOP.010/All.02) must be applied to the reactors and the production equipment during maintenance operations. These labels give the following information:



- Equipment Identification Code
- The Statement "Maintenance in Progress"
- Date when maintenance was initiated
- Process Engineer Signature
- Production Manager Signature

Such labels must remain attached to the equipment for the duration of the maintenance. A facsimile of the label is shown below.

The reactors and the equipment under maintenance shall not be used until the end of the intervention.

P.SOP.012/All.02  
Rev.00  
Date 22.04.2013

## EQUIPMENT ID CODE

.....

# MAINTENANCE IN PROGRESS

Maintenance Initiation Date .....

Process Engineer Signature .....

Production Manager Signature .....

During maintenance, any faulty part as a result of an accident or due to wear and tear, can be replaced with a piece that is identical, in terms of quality and technical characteristics to the damaged part.

In the event that it were not, however, possible to replace the damaged piece with an equivalent piece, it is the task of the Process Engineer to proceed in accordance with procedure G.SOP.012 by presenting the change request: it is possible to implement the change only if the change request is accepted by the departments involved, after appropriate evaluation.

All spare parts are kept in the maintenance department and must be cleaned prior to use, adopting the same cleaning procedure followed for cleaning equipment after maintenance.

It is the responsibility of Maintenance to visually verify the integrity of each filter (filters for the Finishing Department, for the Weighing Room, for nitrogen, for suction), and the correspondence of the filter with the internal specifications prior to installation.

In the case of maintenance that does not require the opening of the reactor hatch, or the introduction of solvents through the pump, it will not be necessary to clean the equipment after maintenance, but it will be sufficient to carry out a thorough cleaning of the premises.



At the end of the maintenance operations, attach the label "To Clean After Maintenance" (P.SOP.010/All.03), with the following information:

- Equipment Identification Code
- The Statement "To Clean After Maintenance"
- Maintenance end date
- Process Engineer Signature
- Production Manager Signature

A facsimile of this label is shown below.

P.SOP.012/All.03  
Rev.00  
Date 22.04.2013

## EQUIPMENT ID CODE

.....

# TO CLEAN AFTER MAINTENANCE

Maintenance End Date .....

Process Engineer Signature .....

Production Manager Signature.....

The cleaning must be verified visually, through feedback from the Batch Production Record, and the presence of the label "Cleaned Following Maintenance" (P.SOP.010/All.04) on the equipment. This label must contain the following information:

- Equipment Identification Code
- The Statement "Cleaned Following maintenance"
- Data of cleaning
- Production Operator Signature
- Production Manager Signature

A facsimile of the label is shown below.



## EQUIPMENT ID. CODE

.....

# CLEANED FOLLOWING MAINTENANCE

Date of Cleaning .....

Production Operator Signature .....

Production Manager Signature .....

The above label must then be stored: it must be attached to the Batch Production Record for the batch produced in the equipment in question after its cleaning (attested by the above label "Cleaned Following Maintenance" P.SOP. 010/All.04).

Upon completion of any maintenance on the reactor or production equipment, this is verified by QA and documented through P.SOP.010/All.05, it must also be inspected by the Production Manager, to examine whether these interventions could have changed operating conditions.

In the case in which the maintenance operations required the closure of the entire production department, all equipment must be cleaned in the manner specified in the corresponding MPR "Cleaning after Maintenance". Moreover, cleaning validation has to be performed, carrying out all the operations indicated in the corresponding "Cleaning department as a result of maintenance" Protocol.

At the end of the maintenance operations, the entire department must also be cleaned as described in the procedure G.SOP.008 "Cleaning of Premises." The same procedure should be applied in the event of activation of new production lines.