



# MAINTENANCE PLAN

AUTHOR

Process Engineer	Signature.....
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VERIFICATION

Quality Assurance Assistant	Signature .....
Production Manager	Signature .....

AUTHORIZATION

Quality Assurance Manager	Signature .....
	Date 13.03.2015

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## Re-Approvals Form

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## 1. REVISION MATRIX

Revision	Date	Subject and Reason for Change
01	06/11/2013	Introduction of R-2801M, Filters F-2101M, F-2201M, F-2801M. Changed the frequency of replacement of water capsule filters.  Date Rev. 00 Withdrawn 08/11/13
02	01/08/2014	Introduction of filters FT01, FT02, FT04, F-1201. Introduction of miller M001. Introduction of freezers and refrigerators.  Date Rev. 01 Withdrawn 05/08/14
03	29/08/2014	Changed the maintenance frequency of the AHUs filters, depending on the filter grade.  Date Rev. 02 Withdrawn 02/09/13
04	29/01/2015	Changed the maintenance frequency of clean rooms interlock system.  Date Rev. 03 Withdrawn 02/02/15
05	13/03/2015	Changed the format on service equipment section. Introduction of reactors R-1101M, R-1201M, R-1301M, automation system DCS-01M, centrifuge CF-1101M, dryer DR-1101M, clean rooms air conditioning HVAC-02M. Introduction of chiller CMT-0101M, Pumps P-0103M, P-0104M, P-0105M and steam generator B-0411M. Removal of chiller CH-01 and tank BTK-RET, boiler B-0301M and Pump P-0102M. Introduction of the wash water level alarm. Date Rev. 04 Withdrawn 17/03/15



## 2. INTRODUCTION

The awareness in issues of maintenance has increased in relatively recent time. A convergence of positions taken by various studies and experience has placed maintenance as a planned process which must be integrated with all the various characteristic features from the moment of design to the moment of operation.

Scheduled maintenance on the one hand establishes in advanced the frequency, method and resources for the maintenance activities, while on the other hand is a process that integrates with the entire usability of the facility and thus characterizes both the performance levels required and the consequential management costs.

The purpose of this maintenance plan is to provide a working tool through which the maintenance knowledge acquired in the design phase, where settings had been analysed and established, can be transferred to the operative stage as an application of a rational maintenance program.

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### 3. METHODS AND DIAGNOSTIC TOOLS

The standard, Uni 10604, stipulates that any maintenance should be the result of the application of diagnostics: it is therefore necessary to use methods of diagnosis that ensure objectivity and comparability.

The level of *general diagnosis* is characterized by simple methods of detection such as:

- Visual detection.
- Detection using simple hand tools.
- Check-lists and simple schedules.
- Information from previous analysis.

The objective of diagnosis at a general level is to obtain general information on the state of the plant as well as, providing a framework for the prediction of failures based on knowledge of the plant characteristics, times and methods of anomalies.

At the level of *specific diagnosis* characterization is done using instrumental detection methods based on written analytical methods, including:

- Destructive tests using instruments.
- Non-destructive tests using instruments.
- Analytical methods such as fault trees, diagnostic trees, ecc.
- Computerized diagnosis through expert systems.

This diagnosis will be made consistently with the available resources, or if the need arises, will be entrusted to a third party.

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## 4. MAINTENANCE COMPANY POLICY

The maintenance of the systems within the company was the subject of a thorough technical and economic analysis, this analysis showed that the optimal solution applicable (and currently applied) consists of a combination of recovery methods, detection and corrections.

This company policy is applied through:

- ✓ SCHEDULED MAINTENANCE
- ✓ INSPECTIVE PREVENTIVE MAINTENANCE
- ✓ EXTRAORDINARY MAINTENANCE
- ✓ INCIDENTAL MAINTENANCE

SCHEDULED MAINTENANCE is carried out after a period of time previously established on the basis of statistical data of a fault (such data can be obtained from the manufacturer and can also be based on experience) and how the machine had been operated. It is performed by outside contractors or by internal operators in the case of simple tasks on devices that have a greater degree of criticality.

INSPECTIVE PREVENTIVE MAINTENANCE is an activity of verifying the state of use and/or functionality of a machine; it assumes that a fault is the final result of deterioration preceded by a series of signals detectable visually or through an instrument, and provides objective criteria for maintenance interventions. It is carried out by the operators of the facility, within the limit of their competence and duty, during the course of normal business activities and is part of the method of use.

EXTRAORDINARY MAINTENANCE interventions provide functional recovery following the detection of a fault that is not predictable in the planning phase and is then carried out with a frequency depending on the contingency.

INCIDENTAL MAINTENANCE consists of planned interventions as a result of failure or malfunction and is carried out, except for primary interventions by specialized external companies.

In the case of a planned downtime of the whole plant or part of the plant, it is possible to suspend scheduled maintenance of the plant or the inactive part. However, these periods of inactivity must not be less than one month, must be removed from the production program and agreed with the management. Before the next reboot of the plant or the inactive portion of the plant, it is required to perform the necessary repair and maintenance activities.

Furthermore, Quality Assurance verify that all maintenance activities are carried out in accordance with the dedicated procedure, P.SOP.010 and other applicable procedures of the company quality system.



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## 5. SERVICE MAINTENANCE

The maintenance service within the company is carried out by a task force dedicated to this service, consisting of: two operators and one manager.

The tasks of this unit are:

- ⇒ Carrying out maintenance operations which are easy to perform and do not pose a risk to the health and safety of the worker.
- ⇒ Apply the requirements of Good Manufacturing Practices (GMP) to the extent applicable and in particular maintain an adequate level of efficiency of the plants in order to minimize the probability of failure.
- ⇒ Detection of anomalies, identifying appropriate corrective actions in a timely manner.
- ⇒ Provide assistance and advice to companies carrying out external interventions.

The personnel assigned assigned in these functions and that usually operate the facility are adequately trained and informed through:

- Operative MAnnuals.
- Internal Procedures.
- Material Safety Data Sheets of the substances involved in the production process.
- Refresher training on the proper use of the facility.

In addition, detailed information on each machine present inside the company is available in the technical archive.

All maintenance activities that go beyond the specific tasks of the servicing or the specific skills of the operators are entrusted to specialized and qualified external companies that are aware of the risks present within the company.

## 6. TECHNICAL ARCHIVE

The archive includes technical support documentation for maintenance activities, and in particular information concerning the structure, operating characteristics and construction of the system.

It must be promptly updated in case of changes and/or new installations, so that at all times its contents accurately reflect the structure of the installation within the company.

The following table displays the contents of the archive:

<i><b>SUBJECT</b></i>	<i><b>CONTENT</b></i>
EQUIPMENT DATA SHEETS	Identification and historical data of equipment and plants present within the company.
USER AND MAINTENANCE MANUALS	Operating manuals for equipment and plants.
CATALOGUES FROM SUPPLIERS	Suppliers advertising materials.
STANDARD OPERATING PROCEDURES	SOPs, qualification data of the plants, planned interventions, procedures for "change control", procedures for specific interventions.
FACILITY VERIFICATIONS	Documents relating to the verification of installations subject to legal regulations.
SAFETY DATA SHEETS	Safety data sheets for materials used in maintenance and substances with which workers may come into contact during operations.
PROJECTS ARCHIVE	Project documentation of the installations (drawings, studies, technical reports, meeting minutes, etc..).
FACILITY VALIDATION	Design qualification, installation qualification, operational qualification.
CALIBRATION PROGRAM	Type, method and frequency of calibration of measuring instruments installed in support of the system and are considered critical from a procedural point of view.
LIST OF SPARE PARTS	Identification data of the systems, machines and components subject to wear and tear.



## **7. SCHEDULED MAINTENANCE**

In this chapter, a section is dedicated to each element of the facility. Each subsection contains the Maintenance table of the components involved that describes the action to be performed and the frequency. The tabels will be compiled during each intervention.



## 7.1. SECTION 0101M

7.1.1. CMT-0101M Chiller +5°C

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Check refrigerant through sight glasses and check for leaks.			Half-yearly	
Check fills and water circuits.			Half-yearly	
Check functionality of the flow state.			Half-yearly	
Check tightness of all electrical terminals.			Annual	

7.1.2. TK-0101M Tank +5°C

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

**7.1.3. P-0101M Primary Tank Pump TK-0101M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

**7.1.4. P-0103M Primary Tank Pump TK-0101M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Test the pressure regulator.			Annual	

**7.1.5. P-0104M Secondary Tank Pump TK-0101M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Test the pressure regulator.			Annual	

**7.1.6. P-0105M Secondary Tank Pump TK-0101M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Test the pressure regulator.			Annual	



## 7.2. SECTION 0201M

### 7.2.1. T-0201M Cooling Tower

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Inspect state of the nozzles.			Half-yearly	
Lubricate crankshaft bearing fan.			Half-yearly	
Wash basin and water filter.			Annual	
Adjust valve and water level.			Annual	
Check and adjust ventilator belts.			Annual	

**7.2.2. CLT-0201M Chiller -25°C**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Check refrigerant through sight glasses and check for leaks.			Half-yearly	
Check fills and water circuits.			Half-yearly	
Check functionality of the flow state.			Half-yearly	
Check tightness of all electrical terminals.			Annual	

**7.2.3. TK-0201M Tank -25°C**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

**7.2.4. P-0201M Water tower circulation pump**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

**7.2.5. P-0202M Water tower primary pump**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

**7.2.6. P-0203M Primary pump refrigeration unit CLT-0201M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	

**7.2.7. P-0204M Secondary pump refrigeration unit CLT-0201M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	
Check the pressure regulator.			Annual	



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### 7.3. SECTION 0301M

#### 7.3.1. TK-0301M Hot water tank

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	

#### 7.3.2. P-0301M Hot water pump

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y Filter on the suction of the pump.			Annual	
Open and close the isolating valves.			Annual	



7.4. SECTION 0401M

7.4.1. B-0401M Steam generator

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Clean combustion components of the burner			Half-yearly	
Open and close the isolating valves.			Annual	
Verify absence scaling or oxidisation on the burner			Annual	
Check integrity status of refractory materials and interior insulation			Annual	
Check tightness of all electrical terminals.			Annual	

**7.4.2. B-0411M Steam generator**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Clean combustion components of the burner			Half-yearly	
Open and close the isolating valves.			Annual	
Verify absence scaling or oxidisation on the burner			Annual	
Check integrity status of refractory materials and interior insulation			Annual	
Check tightness of all electrical terminals.			Annual	

**7.4.3. TK-0401M Condensate tank**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check the cleanliness of the tank, where necessary close the outlet valve and fill with a combination of water and pickling solution. Leave for 30 minutes then drain and rinse.			Annual	
Open and close the isolating valves.			Annual	



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## 7.5. SECTION 0501M

### 7.5.1. C-0501M Compressor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check control and safety equipment.			Half-yearly	
Clean the compressor.			Half-yearly	
Check filters.			Half-yearly	
Check tension-belt			Annual	
Check tightness of all electrical terminals.			Annual	
Open and close the isolating valves.			Annual	

### 7.5.2. CD-0501M Compressed air dryer

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Clean finned surfaces of the condensor.			Annual	
Inspect and clean the filter drain condensate.			Annual	



7.6. SECTION 0701M

7.6.1. SC-0701M Scrubber

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Verify tightness of the suction circuit.			Annual	
Verify tank cleanliness.			Annual	
Clean filter of pump suction.			Annual	
Grease bearings lubrication on fan shaft.			Annual	
Check fan belt tension.			Annual	



7.7. SECTION 0801M

7.7.1. Vacuum pumps (VP-080xM)

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TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Inspect and cleaning fittings, couplings, heat exchanger and cooling system.			Annual	
Replace grease bearings.			Annual	
Nitrogen flushing inspection.			Annual	
Replace gearbox oil.			Annual	
Visual inspection of the exchanger seal.			Annual	
Visual inspection of the tank leaks.			Annual	



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## 7.8. SECTION 1001M

### 7.8.1. WS-1001M Water Softener System

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the Pilot head and verify the internal components.			Annual	
Check and clean the accessories.			Annual	
Simulate regeneration phase.			Annual	
Water hardness setting of outgoing water.			Annual	

### 7.8.2. P-1001M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	

**7.8.3. P-1002M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	

**7.8.4. P-1003M**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	



7.8.5. P-1004M

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Dismantle the dosing head and clean membrane.			Annual	
Replace retention valves.			Annual	
Measure the flow meter.			Annual	
Dismantle and clean the tank level sensor.			Annual	



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7.9. SECTION R-1101M**7.9.1. R-1101M Reactor**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-1101M			Annual	
Clean Y Filter on the suction of the pump P-1101M			Annual	
Check the correct operation of the thermoregulation system.			Annual	



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7.10. SECTION R-1201M7.10.1. R-1201M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-1201M			Annual	
Clean Y Filter on the suction of the pump P-1201M			Annual	
Check the correct operation of the thermoregulation system.			Annual	



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7.11. SECTION R-1301M7.11.1. R-1301M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seals and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	
Visual check for leaks of the pump P-1201M			Annual	
Clean Y Filter on the suction of the pump P-1201M			Annual	
Check the correct operation of the thermoregulation system.			Annual	



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7.12. SECTION R-2201M7.12.1. R-2201M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seales and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	



## 7.13. SECTION R-2301M

7.13.1. R-2301M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seales and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	



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7.14. SECTION R-2401M7.14.1. **R-2401M Reactor**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seales and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	



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7.15. SECTION R-2801M7.15.1. R-2801M Reactor

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for oil leaks from the mechanical seal.			Half-yearly	
Visual inspection of the internal coatings and structural integrity of the reactor body.			Annual	
Check the moving parts, seales and the parts of the glass structure subjected to elevated temperatures.			Annual	
Change the lubricating oil of the motor.			Annual	
Replace the oil of the mechanical seal.			Annual	
Visual check of the hatch gasket.			Annual	
Control enamel interior.			Annual	
Check for leaks in the thermoregulation system.			Annual	
Open and close the valves of the thermoregulation system.			Annual	



7.16. SECTION FILTERS

7.16.1. F-2101M Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

7.16.2. F-2201M Buckner Filter

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the stainless steel components.			Annual	
Visual check of the gaskets.			Annual	

**7.16.3.      F-2801M Buckner Filter**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

**7.16.4.      F-1201 Buckner Filter**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	



**7.16.5.      FT04 Buckner Filter**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	

**7.16.6.      FT01 Lens Filter**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	



**7.16.7.      FT02 Sparkler Filter**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the structural integrity of the filter.			Annual	
Visual inspection of the glass components.			Annual	
Visual check of the gaskets.			Annual	
Check of any deformations: compare the length of the rods and carefully observe the sealing surfaces (any hump or lack of material on the sealings may allow the liquid or dirt to pass through).			Annual	
Check the functionality of the safety valve			Annual	



7.17. SECTION PILOT REACTORS

7.17.1. LR-01

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the glass parts and structural integrity of the reactor body.			Annual	
Check the moving parts, seales and the parts of the glass structure subjected to elevated temperatures.			Annual	

7.17.2. LR-02

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the glass parts and structural integrity of the reactor body.			Annual	
Check the moving parts, seales and the parts of the glass structure subjected to elevated temperatures.			Annual	



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7.18. SECTION DR-1101M7.18.1. DR-1101M Static Dryer

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the internal coating and structural integrity of the dryer.			Annual	
Check the condition of the door seal.			Annual	
Check tightness of the connections and check for leaks.			Annual	
Clean the inside of the condensate collection tank.			Annual	
Internal cleaning of the expansion vessel.			Annual	

7.18.2. P-1701M Circulation pump in dryer sleeve

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y filter on the suction of the pump.			Annual	
Open and close the shutoff valves.			Annual	



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**7.19. SECTION DR-2101M****7.19.1. DR-2101M Static Dryer**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the internal coating and structural integrity of the dryer.			Annual	
Check the condition of the door seal.			Annual	
Check tightness of the connections and check for leaks.			Annual	
Clean the inside of the condensate collection tank.			Annual	
Internal cleaning of the expansion vessel.			Annual	

**7.19.2. P-2701M Circulation pump in dryer sleeve**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual check for leaks.			Annual	
Clean Y filter on the suction of the pump.			Annual	
Open and close the shutoff valves.			Annual	



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7.20. SECTION CF-1101M7.20.1. CF-1101M Vertical Axis Centrifuge

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the grease of the bearings on top and bottom of the basket.			Annual	
Check the bearings on top and bottom of the basket.			Annual	
Check the drive belts.			Annual	
General check of the inertization panel ILP.			Annual	
Check the oil filter of the Hydraulic unit HYU.			Annual	
Check tightness of all electrical connections.			Annual	
Replace the drive belts.			Every ten years	



## 7.21. SECTION MILLER

### 7.21.1. M001 Miller

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check of the tightening of the mechanical connections.			Annual	
Check of the integrity of the electrical connections and of the functionality of the motor.			Annual	
Grease and verify that the bearings operate freely.			Annual	
Check the joint integrity.			Annual	
Check the sealing integrity.			Annual	
Check the grid basket integrity.			Annual	



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## 7.22. SECTION BMS

### 7.22.1. BMS Automation System

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check tightness of all electrical connections.			Annual	
Check for any system errors.			Annual	
Verify drives.			Annual	
Verify input and output signals.			Annual	

### 7.22.2. DCS-01M Automation System

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check tightness of all electrical connections.			Annual	
Check for any system errors.			Annual	
Verify drives.			Annual	
Verify input and output signals.			Annual	



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7.23. SECTION HVAC**7.23.1. AHU1-CP1 Circulation pump HVAC system**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check for any leaks.			Annual	
Clean the Y filter on the aspiration control of the pump.			Annual	
Open and close the shutoff valves.			Annual	

**7.23.2. AHU3-CP1 Circulation pump HVAC system**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visually check for any leaks.			Annual	
Clean the Y filter on the aspiration control of the pump.			Annual	
Open and close the shutoff valves.			Annual	

**7.23.3. AHU1 Air supply/exhaust unit**

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Replace the filters on the exhaust unit.	G4 - Panel Filters			Every two months	
	F9 – Pleated Cell Filters			Half-yearly	
	H13 – Absolute Filters			Annual	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	

**7.23.4. AHU2 Air supply unit**

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	



7.23.5. AHU3 Air supply/exhaust unit

TYPE OF INTERVENTION		Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the filters on the supply unit.	G4 - Panel Filters			Every two months	
	F9 – Rigid Bag Filters			Half-yearly	
	H14 – Absolute Filters			Every six years	
Replace the filters on the exhaust unit.	G4 - Panel Filters			Every two months	
	F9 – Pleated Cell Filters			Half-yearly	
	H13 – Absolute Filters			Annual	
Check controls and safety equipment.				Half-yearly	
Check fan belt tension.				Annual	
Clean grills on air input\output.				Annual	



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**7.23.6. Clean rooms interlock system**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check the functionality of door indicator lights.			Half-yearly	
Check the functionality of door electric interlocks.			Half-yearly	



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## 7.24. Service Circuits

### 7.24.1. Steam/Condensate circuit

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check calibration of pressure regulator.			Annual	
Check the efficiency of the condensate drains.			Annual	
Check for leaks in the circuit.			Annual	
Clean Y filters.			Annual	

### 7.24.2. Cold water circuit (+5°C)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check calibration of pressure regulator.			Annual	
Check for leaks in the circuit.			Annual	
Clean Y filters.			Annual	

**7.24.3. Chilled water circuit (-25°C)**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check calibration of pressure regulator.			Annual	
Check for leaks in the steam circuit.			Annual	
Clean Y filters.			Annual	

**7.24.4. Hot water circuit**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for leaks in the circuit.			Annual	
Clean Y filters.			Annual	

**7.24.5. Nitrogen circuit**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Check for leaks in the circuit.			Annual	
Replace cartridge filters.			Annual	

**7.24.6. Reactors water supply circuit**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace softened water filters.			Every three months	
Check for leaks in the circuit.			Annual	

**7.24.7. Storage tanks, wash water and process wastewater**

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Verification, through the hydrostatic pressure measuring instrument, of any losses from the tank.			Every two years	
Verification of the level sensor alarm.			Every two years	



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## 7.25. Service Equipment

### 7.25.1. Hoists

Lubricate the gear. Spread the lubricant and keep the gear thoroughly covered with the cart.	Visually check hoist integrity.	Check integrity and state of hook.	Maintenance Date	Operator Signature	Frequency
PR-01 (Maintenance Workshop)					
Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
PR-1P (Production area 1P)					
Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
PR-1101M (Room 11C)					
Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
PR-2101M (Room 12C)					
Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual

Maintenance Director Signature

Date

**7.25.2. Transpallets**

Duplicate this page if necessary

Page \_\_\_\_ of \_\_\_\_

ID	Top up oil pump.	Lubricate roller bearings and steering wheels.	Lubricate the guide of the control lever that drives the pump.	Maintenance Date	Operator Signature	Frequency
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual

Maintenance Director Signature

Date

**7.25.3. Flexible Pipes**

Duplicate this page if necessary

Page \_\_\_\_ of \_\_\_\_

ID	Check integrity of tubing.	Check screws on attachment ties.	Maintenance Date	Operator Signature	Frequency
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
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	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Half-yearly

Maintenance Director Signature

Date



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**7.25.4. Fume hood QC1 and QC2**

ID: FH01 (QC2)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the pre-filters.			Half-yearly	
Replace the Active Carbon filters.			Annual	
Front air flow measurement using methods and acceptance criteria regulated by the following technical standards: DIN 12924 Teil 1-4 and BS 7258 Part 1-4.			Annual	



ID: FH02 (QC1)

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace the pre-filters.			Half-yearly	
Replace the Active Carbon filters.			Annual	
Front air flow measurement using methods and acceptance criteria regulated by the following technical standards: DIN 12924 Teil 1-4 and BS 7258 Part 1-4.			Annual	

**7.25.5. Maintenance of freezers and refrigerators**

Duplicate this page if necessary

Page \_\_\_\_ of \_\_\_\_

ID	Check the door seal	Clean the condenser coil	Manual defrost the unit	Maintenance Date	Operator Signature	Frequency
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
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	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
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	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual
	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>	Ok <input type="checkbox"/> No <input type="checkbox"/>			Annual

Maintenance Director Signature

Date



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## 7.26. SAMPLING ROOM MAINTENANCE

### 7.26.1. Sampling room extractor hood

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Replace G4 filter on suction hood.			Half-yearly	



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## 7.27. BUILDING MAINTENANCE

### 7.27.1. MAINTENANCE OF BUILDINGS INTERIOR

TYPE OF INTERVENTION	Maintenance Date	Operator Signature	Frequency	Maintenance Director Signature
Visual inspection of the integrity of walls and roofs, absence of cracks, coating uniformity, absence of moisture patches.			Half-yearly	
Visually check glass integrity			Half-yearly	
Visually check doors integrity			Half-yearly	
Verify functionality of door handles			Half-yearly	
Check environment lumination			Half-yearly	
Check circuit breakers functionality			Half-yearly	
Verify functionality of emergency lighting			Half-yearly	
Check load applied to electric outlets			Half-yearly	



8. APPENDIX A: REPLACEMENT LABELS ON SOFTENED WATER FILTERS



**SOFTENED WATER FILTER**  
**SUBSTITUTION**

MN.SOP.001  
Rev 05  
Date 13/03/2015

FILTER	
TOT. LITER COUNTERS on Installation	
DATE INSTALLATION	
DATE OF NEXT SUBSTITUTION	
PRODUCTION SIGNATURE	
QA SIGNATURE	



9. APPENDIX B: LABELS FOR FUME HOOD CAPS AND FILTERS SUBSTITUTION



FUMEHOOD/FILTERS CHECK

MN.SOP.001  
Rev 05  
Date 13/03/2015

Date of check	
Date of next check	
Date of carbon filter change	
Date of next carbon filter change	
Date of substituting pre-filters	
Date of next pre-filters substitution	
PROCESS ENGINEER SIGNATURE	
QA SIGNATURE	



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**10. APPENDIX C: LABELS FOR PROCESS FLUIDS AND SERVICES**

<b>Label Color</b>		<b>Fluid</b>
<b>Text</b>	<b>Background</b>	
White	Green	Chilled Water
White	Green	Cooling Water
White	Green	Hot Water
White	Green	Softened Water
White	Grey	Steam
White	Blue	Compressed Air
White	Yellow/beige	Nitrogne
White	Brown	Reactors Loading/Discharge
White	Yellow	Process Vacuum
White	Yellow	Service Vacuum
White	Yellow	Emergancy Relievers
White	Yellow	Service Vents

**11. APPENDIX D: DATA COLLECTION SHEET****Preventive Maintenance Checks: Fault Management**

Reference Test and fault detected

Rif. Document	Rif. Equipment	Id	Part of equipment	Description of Intervention	Maintenance Date

Type of Maintenance (Internal/External)	Planned Frequency of Intervention (months)	External Company (if applicable)	Start Date	Planned Closing Date	Closing Date

**Anomaly Noticed**


Maintenance Op.	Date	Process Engineer	Date	Approval	Date

**Description of Recovery Work**


Maintenance Op.	Date	Process Engineer	Date	Approval	Date

**Description of Materials Required for Restoration**


Maintenance Op.	Date	Process Engineer	Date	Approval	Date