

**STANDARD OPERATING PROCEDURE**



<b>SOP NUMBER:</b> 6.1027	<b>SOP VERSION:</b> 1.0
<b>EFFECTIVE DATE:</b> 17/02/2005 03:20:00 PM	
<b>SOP TITLE:</b> Hazardous Deliveries - Loading and Un-Loading Procedure	

**SIGNATURE INFORMATION**

	<b>SIGNATURE</b>	<b>DEPARTMENT</b>	<b>DATE</b>
Originated By:	Vicky Bow	Environmental Health & Safety	17/09/2004 11:55:00 am
Reviewed By:	John Toner	Maintenance Engineering	27/09/2004 05:43:21 pm
Reviewed By:	Tony Carter	Environmental Health & Safety	06/10/2004 09:25:27 am
Approved By Quality:	Linda Nolan	Quality Assurance	07/10/2004 08:59:57 am

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**FOR INFORMATION**

Version	Revision Details	Effective Date
0	Original	

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## 1.0 PURPOSE

To identify the necessary operational, safety and environmental precautions required when loading and off loading hazardous deliveries.

## 2.0 SCOPE

This procedure relates to the following activities:

- Delivery of Sulphuric Acid – 50% Concentration and Sodium Hydroxide (Caustic Soda) – 30% Concentration in 1000L IBC units – cross pumped to the effluent dosing tanks located in the effluent dosing hut.
- Delivery of Hydrochloric Acid – 30% Concentration and Sodium Hydroxide (Caustic Soda) – 30% Concentration in Pfizer owned IBC units to the maintenance delivery bay located outside the plant room.
- Delivery of Diesel Oil – cross pumped to the Gas Oil Tank located in the tank farm adjacent to the effluent balancing tank.
- Loading of Special Waste Collections in 200L Drums and 400L Wheelie Bins into the waste truck/container.

## 3.0 ORGANISATIONAL UNITS AFFECTED

EHS  
Security  
Maintenance Engineering  
Warehouse

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## 4.0 SAFETY

- 4.1 Refer to the relevant MSDS prior to loading/off loading the delivery. Copies of the relevant MSDS's are available in the EHS Department.
- 4.2 In the event of spillage refer to SOP 6.1007 Spillage Control.
- 4.3 In the case of cross pumping operations to the effluent dosing tanks involving acid/caustic ensure that the contractor is wearing appropriate Personal Protective Equipment (PPE), at the minimum chemical resistant gloves, goggles/face mask and a chemical resistant suit. At a minimum the EHS supervisor must be wearing safety goggles, white coat and safety gloves and must remain well back from the connection points during the delivery process.
- 4.4 For all other deliveries delivery contractors and Pfizer representative supervisors should wear the following PPE: Safety goggles, Safety shoes and Gloves must be worn at minimum.
- 4.5 In the event of an accident/near miss, report immediately to the EHS manager or nominated deputy and compile an Accident/Near Miss Report as soon as possible in line with SOP 6.0205.
- 4.6 Deliveries of Concentrated Acid and Caustic must be kept separate and must not be allowed to mix as this would produce a violent exothermic reaction.

- 4.7 All operations below involve the activation of the fire-water retention valve switch in order to divert all surface water to the firewater retention tank during loading and un-loading operations. This prevents any surface water which may become contaminated in spill occurrences from entering the nearby Deansgrange Stream  
The firewater retention valve switch is located on the outside of the firewater retention control panel. The key for this switch is located in the EHS Department.

## 5.0 REFERENCES/DOCUMENTATION

- 6.0205 Accident - Occupational Illness and Near Miss Reporting and Investigation
- 6.1001 Maintenance and Emptying of Bunded Areas in the Pharmaceutical Plant
- 6.1007 Spillage Control
- 6.1025 Waste Management Policy

## 6.0 RESPONSIBILITIES

- 6.1 It is the responsibility of the EHS Department to:
- Order Acid/Caustic for the effluent dosing hut. Acid/Caustic must only be ordered when the level in the specific receiving tank is <20% volume, in order to ensure that there is sufficient space in the tank to accept delivery.
  - Oversee delivery of these chemicals in compliance with section 7.1 of this procedure.
  - Oversee loading of special waste consignments in line with Section 7.4 of this procedure.
- 6.2 It is the responsibility of the Maintenance Engineering Department to:
- Order Acid /Caustic for the De-ionised Water System
  - Oversee delivery of these chemicals in compliance with section 7.2 of this procedure.
  - Order Diesel as required.
  - Oversee delivery of Diesel Oil in line with section 7.3 of this procedure.
- 6.3 It is the responsibility of the Warehouse Personnel to:
- Unload acid/caustic IBC Units as required.
- 6.4 It is the responsibility of the Security Department to:
- Inform the relevant Departments as detailed in sections 6.1-6.3 above of the arrival on site of the delivery/collection vehicle.

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## 7.0 PROCEDURE

### 7.1 Delivery of Acid and Caustic to the Effluent Dosing Hut as overseen by the Environmental Officer or nominated deputy.

- 7.1.1 Ensure that sufficient space is available in the acid and caustic tanks to receive delivery. This is completed by obtaining a print out of the tank levels from the BMS System.
- 7.1.2 Remove the inlet caps/covers – keys are located in the EHS Department. (Spare Keys are located in Security for an Emergency Situation)
- 7.1.3 Remove **the** external bund covers to catch small spills during cross pumping operations.
- 7.1.4 **Initiate** the fire water retention valve switch.
- 7.1.5 Ensure that all valves on the storage system are correctly set and that the delivery pipe is in good order with respect to threads and pipe integrity prior to commencement of delivery.
- 7.1.6 Ensure that all connections are secure, supervise the off-loading pumping operation and sign the necessary documentation when complete.
- 7.1.7 Upon cessation of the pumping, the delivery IBC is partially filled with water. This water is then pumped through the lines into the acid/caustic tanks in order to rinse the lines. The lines are then rinsed additionally with water and emptied into the collection bund. This rinsing process is carried out after the charging of each of the chemicals.
- 7.1.8 Secure the inlet caps/covers and ensure valves are left in the correct closed position.
- 7.1.9 Re-set the fire water retention valve switch.
- 7.1.10 The bund contents must be cross pumped to the effluent collection sump by the Maintenance Engineering Department Waste Handlers in line with SOP 6.1001.

### 7.2 Delivery of Acid and Caustic in 1000L IBC units to the maintenance engineering loading bay as overseen by the Maintenance Engineering Department.

- 7.2.1 Ensure that the maintenance loading bay is clear to accept the delivery and that only personnel/trucks/equipment required to be present during the delivery are in the vicinity of the loading bay.
- 7.2.2 Initiate the fire water retention valve switch to divert all surface water to the firewater retention tank during the cross pumping operation.
- 7.2.3 Place bund cover on the nearest surface water drain to the off-loading location. This drain is located beside the pump house and the drain cover is located inside **the** pump house.
- 7.2.4 Cordon off the main footpath surrounding the loading bay using safety barriers and divert pedestrians into/out from the building via alternative access doors during the off loading operation.
- 7.2.5 Oversee unloading of the IBC units to the loading bay by the Warehouse representative.
- 7.2.6 Removed the delivered IBC Units from the loading bay immediately, to within the building storage location.
- 7.2.7 Once the off-loading operation has been completed, remove the safety barriers, drain cover and re-set the fire water retention valve switch.

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### **7.3 Delivery of Acid Diesel Deliveries to the Gas Oil Tank as overseen by the Environmental Officer, or nominated deputy.**

- 7.3.1 Ensure that sufficient space is available in the diesel tank to receive the delivery.
- 7.3.2 Initiate the fire water retention valve switch to divert all surface water to the firewater retention tank during the cross pumping operation.
- 7.3.3 Place bund cover on the nearest surface water drain to the off-loading location. This drain is located beside the pump house.
- 7.3.4 Oversee the cross pumping operation and sign the necessary documentation upon completion.
- 7.3.5 Once the cross pumping operation has been completed, remove the drain cover and re-set the fire water retention valve switch.

### **7.4 Loading of Special Waste Shipments as overseen by the Environmental Officer, or nominated deputy.**

- 7.4.1 Initiate the fire water retention valve switch to divert all surface water to the firewater retention tank during the waste loading operation.
- 7.4.2 Place bund cover on the nearest surface water drain to the off-loading location. This drain is located beside the waste compactor. This drain cover is located in the spill response hut in the Waste Storage Area.
- 7.4.3 Oversee the loading operations and sign the necessary documentation as per SOP 6.1025.
- 7.4.4 Once the loading operation has been completed, remove the drain cover and re-set the fire water retention valve switch.

### **8.0 SPILLAGE**

- 8.1 In the event of a large spillage occurring, the operation is ceased and the Emergency Response for Spills is put into effect.

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SOP NUMBER: QCG009	SOP VERSION: 6.0
EFFECTIVE DATE: 02/10/2003 11:25:00 AM	
SOP TITLE: DISPOSAL OF LABORATORY WASTE	

**SIGNATURE INFORMATION**

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Originated By:	Vicky Bow	Environmental Health & Safety	11/09/2003 08:41:38 am
Reviewed By:	Deirdre Jones	Quality Control	11/09/2003 08:44:49 am
Reviewed By:	Tony Carter	Environmental Health & Safety	11/09/2003 06:11:34 pm
Approved By Quality:	Ann Whelan	Quality Assurance	12/09/2003 11:08:19 am

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*Chemistry  
Inspector  
Environmental Health & Safety  
Entry FH 02/10/03*

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SOP NUMBER: QCG009

SOPVERSION: 6.0

SOP TITLE: DISPOSAL OF LABORATORY WASTE

NO.	REVISION DETAILS	EFFECTIVE DATE
ORIG.	Original	30.07.92
Rev. 1	Change 'Hydranal" to "Turbotitrator Waste". Change responsibility for official log to QA Manager. Include Reference to Deep Burial bins. Change Safety Statement. Incorporate QCG005, 'Collection and Storage of Toxic Waste and Non-toxic Waste requiring Deep Burial'. Include p-Nitrophenol	10.06.94
Rev. 2	Include new waste SOP's 6.1002, 6.1003 and 6.1004. Void 6.0412. Change Requirements, Safety Statement and Storage facilities.	24.06.96
Rev. 3	Amended number of waste classifications from 7 to 8 for toxic waste. Included sections on segregation of waste from Clinafloxacin, Ketalar, Suramin, Heparin for incineration.	25.10.96
Rev. 4	Included CEREBYX in the section on the segregation of waste. Changed classification of wastes to Hazardous or non Hazardous to comply with current regulations.	15/05/97
Rev. 5	Change reference of Environmental officer to Environmental, Health and Safety Manager. Include statement on waste from sterility testing.	12/07/00
Rev. 6	Updated Section 6.3 to include UK-292,663 Fluconazole Prodrug	09/11/00
Rev. 7	Revised to include provision for Azithromycin for Injection 500mg/vial( 100mg/ml when reconstituted)/Azithromycin Powder for Solution 500mg/vial(100mg/ml when reconstituted), other minor text changes to safety statement.	07/06/01
Rev. 8	Updated to include Voriconazole for Infusion 10mg/ml when reconstituted, 200mg/Vial and Sulphobutyl Ether $\beta$ -Cyclodextrin Sodium (SBECD). Minor text changes to Section 6.3, List of Hazardous Waste.	07/01/02
Rev. 9	Complete re-write to separately designate Waste Streams arising from the Microbiology Laboratory and the Chemistry Laboratory, Waste Classifications, Waste Bins and the Final Disposal Method. Updated to include reference to the Pfizer Waste Special and Non-Special Designations in line with the Pfizer Waste Management Guideline 19.	

FOR INFORMATION

SOPSTATUS: Effective

EFFECTIVE DATE: 02/10/2003 11:25:00 AM

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## 1.0 PURPOSE

To define the different Waste Streams produced in the Microbiology and Chemistry Laboratory and describe the Specific Disposal Route for each Waste Stream.

## 2.0 SCOPE

This SOP details wastes resulting from the use of chemicals and reagents for product testing, in addition to product waste surplus to testing requirements.

## 3.0 ORGANISATIONAL UN-ITS AFFECTED

- Chemistry Laboratory
- Microbiology Laboratory
- QCI
- EHS
- Maintenance/ Engineering Department – ‘Waste Handlers’

## 4.0 REFERENCES

Municipal Wastes produced on site are detailed in SOP 6.1004 – Disposal of Municipal Waste at Pfizer.

All Waste produced by Production is referenced in the following SOP's:

- 6.1023 – Disposal of In Process and Finished Product Waste and
- 6.1021 – Disposal of Waste Bovine Material

Maintenance and Project related wastes produced on site are detailed in SOP 6.1024 – Disposal of Maintenance and Project Related Waste.

The management of waste on site and the shipment of waste off site is detailed in Sop 6.1025 Waste Management Policy.

All waste streams in this SOP are classified according to the Pfizer Corporate EHS Waste Management Guideline 19.

The autoclaving of waste in the Microbiology Laboratory is detailed in SOP QCM 063 – Operation of the Fedagari Steam Steriliser.

## 5.0 RESPONSIBILITIES

It is the responsibility of the EHS department to classify all waste streams generated on site and to ensure that they are adequately disposed of in accordance with applicable legislation, the Site IPC licence and the Pfizer Corporate EHS Waste Management Guideline.

It is the responsibility of the EHS Department to schedule the shipment of all special wastes detailed in this SOP off site. The requirements and documentation associated with these shipments are detailed in the Waste Management Policy SOP 6.1025.

It is the responsibility of the Laboratory Supervisors to ensure that all waste bins are adequately labelled.

It is the responsibility of the Laboratory Personnel to segregate waste streams into suitable containers in line with the requirements of this SOP and to label wastes accordingly.

It is the responsibility of the Waste Handlers to collect waste from the designated bins in Microbiology Laboratory and the Chemistry Laboratory and dispose of the waste to the final storage containers as detailed in sections 7.1.2 and 7.2.2 below.

## 6.0 SAFETY

Do not mix chlorinated and non-chlorinated solvents

Handle all special waste with caution using personal protective equipment including safety glasses, gloves and safety shoes at minimum. Consult MSDS before handling. Where possible carry out open handling of chemicals or biological waste in a fumehood or biosafety cabinet.

Waste chemicals have the same properties as the virgin material – ensure you are familiar with the hazards and precautions to be taken before handling any waste, particularly special waste.

Handle all biological materials as if capable of transmitting disease.

All waste should be appropriately and clearly labelled to identify the primary associated hazard. Store waste according to hazard class.

Ensure all “sharps” are disposed of in sharp bins.

Leaking containers should be identified and immediately notified to the Departmental Manager responsible. Procedure 6.1007 must then be followed to contain the leak.

Particular care must be taken when transporting containers of special waste. Winchester must be carried in a Winchester carrier.

Ensure you use the correct manual handling technique – follow SOP 6.0911 at all times.

Report all near miss or accidents to your supervisor immediately and fill in a report as soon as possible. Ref. 6.0205

Waste Handlers should wear Latex gloves covered by Hydro Kevlar Gloves (cut resistant) when collecting all waste from the Waste Vial Bins and Non-Product Contact Glass Waste due to the potential of Handling Broken Vials/Glass.

Waste Handlers should wear PAPR respirators when decanting solvents into 200L drums in preparation for disposal off site.

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## 7.0 PFIZER WASTE DESIGNATION

Pfizer Waste is classified as either 'Special Waste' or 'Non-Special Waste' in line with the Pfizer Corporate Waste Management Guideline 19. A definition for this terminology is detailed below:

Special Waste is any wastestream comprised of biological, radioactive or pharmaceutical wastes. A waste is also considered a Special Waste if the total wastestream volume is more than 100 kg per year and it contains any hazardous constituents in concentrations of greater than 0.1 percent, that could adversely impact public health or the environment, if mismanaged.

Non-Special Waste is any wastestream comprising of non-hazardous constituents. A wastestream will also be considered non-special if the total wastestream volume is less than 100 kg per year and it can be demonstrated that it does not contain any hazardous constituents in concentrations of greater than 0.1 percent, that could adversely impact public health or the environment, if mismanaged.

## 8.0 PROCEDURE

For the purpose of this procedure the Waste Streams produced in the Microbiology Laboratory and Chemistry Laboratory are described separately below.

### 8.1 Microbiology Laboratory Waste

#### 8.1.1 Waste Streams

The following waste streams detailed below are produced in both the Microbiology Laboratory and the La Calhene Room.

- Microbiological Waste

Microbiological Waste is segregated as follows:

**Bagged Waste** – This waste comprises of biological cultures, positive growth samples (air strips, agar contact plates, agar settle plates), API kits, steritest kits, plastic pipettes, endotoxin testing disposables and in process biological samples.

This waste is placed in red biohazard bags at each workstation. It is the responsibility of the microbiology laboratory personnel to ensure that all microbiological bagged waste has been autoclaved at 121°C and 15Lbs. pressure for approximately 1 hour as per SOP QCM 063, prior to collection by the waste handlers. This waste is stored in the in the designated 400L wheelie bins in the -20°C waste freezer prior to disposal.

**Glassware** – This waste is comprised of glassware containing positive swabs, seeded peptone controls, test-tubes containing BI's and other non-disposable glassware. This glassware is placed on the trolley adjacent to the autoclave, in the microbiology laboratory until autoclaved. It is the responsibility of the microbiology laboratory personnel to ensure that all glassware is autoclaved at 121°C and 15Lbs. pressure for approximately 30 minutes, as per SOP QCM 063. This glassware is then washed, dried and re-used.

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#### . Liquid Product Waste

Liquid product waste from bioburden testing, endotoxin testing and particulate matter testing is segregated and placed into individual labelled nalgene containers for each product waste stream.

Liquid waste resulting from sterility testing of Voriconazole for Infusion 200mg/vial and Azithromycin for Injection 500mg/vial is segregated into individual labelled nalgene containers. Liquid waste resulting from sterility testing of all other products is placed into a nalgene container labelled as mixed product liquid waste.

All liquid waste is collected by the waste handlers and placed in 200L Drums for disposal by incineration at an approved facility.

- Waste Vials

This includes in process and finished product samples surplus to testing requirements and waste vials from product testing. These waste vials are placed in the designated waste vials bins and are collected by the waste handlers upon request from the microbiology laboratory personnel.

Additionally, waste vials and waste sterility kits from sterility testing are placed in the waste vial bin in the La Calhene room, for collection by the waste handlers.

- Sharps

This waste stream consists of waste needles and syringes from microbiological testing. These sharps are placed in dedicated sharps containers and are removed by the waste handlers to dispose to the 400L wheelie bins in the -20°C waste freezer.

- Non-Contaminated Glass Waste

Non-contaminated glass waste is placed in the designated bins and is collected by the waste handlers on an ongoing basis.

- General Waste

All non-contaminated waste including plastic and paper packaging is placed in the designated general waste black bins in the laboratory.

This waste is collected on an ongoing basis by the waste handlers and disposed of to the site waste compactor as per SOP 6.1004.

- Paper for Recycling

Paper for Recycling is placed in the designated paper recycling bins, collected by the waste handlers on a timely basis and placed in the paper recycling wheelie bin for collection by an external waste contractor.

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8.1.2 **Waste Stream Handling and Disposal Route**

Waste Stream	Pfizer Designation	Bin J Container	Final Disposal Container	Disposal Method
Microbiological Bagged Waste	Special	Biological Waste Bins	400L Wheelie Bins in the -20°C Freezer	Industrial Autoclaving to render non-infectious, shredding and landfill.
Liquid Product Waste	Special	Individual Nalgene Containers	200L Drum in the Trash Room	Incineration
Waste Vials	Special	Waste Vial Bins	200L Drum in the Trash Room	Incineration
Sharps Waste	Special	Sharps Bin	400L Wheelie Bins in the -20°C Freezer	Industrial Autoclaving to render non-infectious, shredding and landfill.
Non-Product Contact Glass Waste	Non-Special	Non-Product Contact Glass Waste Bin	Glass Recycling Banks / Site Compactor	Recycling/Landfilling
General Waste	Non-Special	Black General Waste Bin	Site Compactor	Landfill
Waste Paper	Non-Special	Recycling Bin	100L Wheelie Bin for Paper Waste Recycling	Recycling

8.2 **Chemistry Laboratory Waste**

8.2.1 **Waste Streams**

The following waste streams detailed below are produced in the Chemistry Laboratory, HPLC Room and the Dehumidified Room.

- **Biological Waste**

This waste stream consists of biological product contact waste including: weigh boats, pipettes, biological waste contaminated wipes, biological raw material surplus to testing requirements and biological contact waste glass.

This waste stream is placed in suitably labelled RED bins and is collected by the waste handlers on a daily basis and placed in the designated 400L wheelie bins in the -20°C waste freezer.

- **Pharmaceutical Contact Waste**

This waste stream consists of the pharmaceutical product and chemical contact waste including: weigh boats, pipettes, gloves, filter paper, IR discs, wipes and any waste that has come in contact with pharmaceutical products/raw materials.

This waste is placed in suitably labelled YELLOW bins and is collected by the waste handlers on a daily basis and placed in 200L drums for incineration.

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- Waste Vials

Both waste pharmaceutical product and waste biological product vials are placed in suitably labelled BLUE waste vial bins. This includes both unopened and opened waste vials, which are surplus to testing requirements. Pharmaceutical contact waste glass may also be placed in these bins.

These bins are emptied on a daily basis by the waste handlers and placed in 200L drums for incineration.

- Liquid Product Waste

This consists of liquid product resulting from physical testing. Liquid product waste is segregated into 20L flammable containers specifically labelled for each waste stream, for collection by the waste handlers. This waste is placed into 200L drums for incineration-

- \* Non-Chlorinated Solvent Waste

This waste stream comprises of acetonitrile, methanol, sodium dodecyl sulphate (SDS), acetone, iso propanol, formamide, methyl glycol and hydranal composites 5 and 2 resulting from HPLC testing and moisture analysis. Non-Chlorinated Solvent Waste is held in labelled 20L flammable containers in the laboratory for collection by the waste handlers and is placed in 200L drums for incineration.

- Chlorinated Solvent Waste

This waste stream is comprised of dichloromethane, chloroform and dithiazone waste from product testing. Chlorinated solvent waste is held in a labelled 20L flammable container in the fume hood in the chemistry laboratory.

The waste handlers will collect this waste stream for disposal to 200L drum upon instruction from the chemistry laboratory personnel.

- . Sharps

This waste stream consists of waste needles and syringes from product testing. These sharps are placed in dedicated sharps containers and are removed by the waste handlers to dispose to the 400L wheelie bins in the -20°C waste freezer.

- Metal Solutions

Metal solutions from water testing including copper sulphate, lead solutions, arsenic solutions, and stannous chloride solutions should be placed in glass Winchester and placed in the waste cabinet to be collected by the waste handlers upon instruction from the Chemistry laboratory personnel.

- Expired Solutions

AU expired solutions and miscellaneous waste solutions for disposal should be placed in the waste cabinet in the chemistry laboratory and logged in the Waste Log Book.

It is the responsibility of the Waste Handlers to move waste from these cabinets and place it in the external waste cabinets in the waste area on an ongoing basis.

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- Empty Plastic Reagent Bottles / Empty Glass Winchester

Empty reagent bottles should be rinsed thoroughly by the laboratory personnel. Rinsed plastic reagent bottles are placed in the general waste BLACK bin for disposal and rinsed glass Winchester, as they arise are collected by the waste handlers.

- Non-Product Contact Glass

Non product contact glass waste is placed in the designated bins and is collected by the waste handlers on an ongoing basis.

- General Waste

All non-contaminated waste including packaging from incoming materials (non-product contact) and rinsed plastic reagent bottles is placed in the designated BLACK general waste black bins in the laboratory.

This waste is collected on an ongoing basis by the waste handlers and disposed of to the site waste compactor, as per SOP 6.1004.

- Paper for Recycling

Paper for recycling is placed in the designated paper recycling bins, collected by the waste handlers on a timely basis and placed in the paper recycling wheelie bin for collection by an external waste contractor.

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8.2.2 Waste Stream Handling and Disposal Routes

Waste Stream	Pfizer Designation	Bin / Container	Final Disposal Container	Disposal Method
Biological Waste	Special	RED Biological Waste Bins	400L Wheelie Bins in the -20°C Freezer	Industrial Autoclaving to render non-infectious, shredding and landfill.
Pharmaceutical Contact Waste	Special	YELLOW Pharmaceutical Contact Waste Bins	200L Drum in the Trash Room	Incineration
Waste Vials	Special	BLUE Waste Vial Bins	200L Drum in the Trash Room	Incineration
Liquid Product Waste	Special.	20L Flammable Containers	200L Drum in the Waste Area	Incineration
Non-Chlorinated Solvent Waste	Special	20L Flammable Containers	200L Drum in the Waste Area	Incineration
Chlorinated Solvent Waste	Special	20L Flammable Containers	200L Drum in the Waste Area	Incineration
Sharps Waste	Special	Sharps Bin	400L Wheelie Bins in the -20°C Freezer	Industrial Autoclaving to render non-infectious, shredding and landfill.
Metal Solutions	Special	Glass Winchester	Glass Winchester in Designated Waste Cabinets	Incineration
Expired Solutions	Special	Original Containers	Designated Waste Cabinets	Incineration
Empty Plastic Reagent Bottles / Empty Glass Winchester	Non-Special	Plastic - BLACK General Waste Bin Glass - Compactor	Site Compactor	Landfill
Non-Product Contact Glass	Non-Special	Non-Product Contact Glass Waste Bin	Glass Recycling Banks / Site Compactor	Recycling / Landfilling
General Waste	Non-Special	BLACK General Waste Bin		
Waste Paper	Non-Special	Recycling Bin	100L Wheelie Bin for Paper Waste Recycling	Recycling

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### 8.3 Sharps Waste

It is the responsibility of the EHS Department to provide the Microbiology and Chemistry Laboratory with suitable UN containers for collecting sharps waste.

It is the responsibility of the waste handlers to weigh all sharps containers prior to placing them in the designated 400L wheelie bins in the -20°C freezer and to report these weights to the Environmental Officer to log on the EHS Waste Database.

### 8.4 New Waste Streams

It is the responsibility of the Microbiology and Chemistry Laboratory Managers to inform the Environmental Officer of any new waste streams that arise so that the Environmental Officer can classify the waste stream and determine the most suitable disposal route for the waste.

### 8.5 Containers for the Collection of Special Waste

8.5.1 Waste containers designated for special wastes should always be checked prior to use in order to ensure that they are suitable for the specific waste stream, are labelled and are leak and corrosion free. Containers must be properly closed after use.

8.5.2 Once a container is full it must be taken to the designated storage area at the earliest possible time. The department generating the waste is responsible for ensuring that waste is removed from the area. Waste handlers can be contacted to remove waste to the designated storage areas.

8.5.3 All designated areas for the storage of special wastes must be bunded or suitably contained.

### 8.6 Waste Log Book

It is the responsibility of the Laboratory Personnel to log expired solutions and miscellaneous waste as it is deposited in the Chemistry Laboratory Waste cabinet.

The Waste Handlers will sign this log upon transferral of this waste to the external waste cabinets.

### 9.0 WASTE SHIPMENT OFF SITE

All requirements associated with the shipment of laboratory waste off site is detailed in SOP 6.1025.

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STANDARD OPERATING PROCEDURE



SOP NUMBER: 6.0361	SOP VERSION: 3.0
EFFECTIVE DATE: 2910812002 11:25:00 AM	
SOP TITLE: CALIBRATION PROGRAMME	

SIGNATURE INFORMATION

	SIGNATURE	DEPARTMENT	DATE
Originated By:	Grace Healy	Maintenance Engineering	20/08/2002 09:08:54 am
Reviewed By:	John Toner	Maintenance Engineering	20/08/2002 09:16:40 am
Reviewed By:	Mary Casey	Environmental Health & Safety	20/08/2002 09:44:23 am
Approved By Quality:	Susan Neenan	Quality Assurance	20/08/2002 10:30:09 am

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Maintenance Engineering REISSUED 24/4/03 J.S.V.  
IN 29.8.2002

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SOP NUMBER: 6.0361

SOP VERSION: 3.0

SOP TITLE: CALIBRATION PROGRAMME

No.	Revision Details	Effective Date
ORIGINAL	Written to replace ENG-001. Procedure updated for PQ0501. Procedure made a plant procedure instead of a departmental procedure. ENG-001 to be voided.	11/6/98
Rev. 1	Some minor text changes needed to points 7.10 text removed, 7.16 a Notice of Event Report changed to Out of Tolerance Report, 8.3 E.G. and instrument changed to EG. An instrument, 10.1,10.3and 10.5 text removed, 12.3 tractability changed to traceability 12.4 text added "Corporate Quality Safety <b>and</b> Environmental Assessment (CQSEA) . Appendix 1 Notice of Event Report changed to Out of Tolerance Report	6/11/98
Rev. 2	Text added to the procedure In point 5.3 (e) the following text added. Monthly reporting of overdue calibrations. In point 5.3 (f) the following text added. Include requirement to provide advance notice of calibrations approaching their due date.	23.04.99
Rev. 3	Text changes and alterations made to procedure. Point 7.15 out of tolerance report raised. Point 8.8 text change Point 13.1,7.20. Deleted text 'Report' changed wording. Point 14 deleted this section as no longer required Made changes to date when tolerance exceeded section Inserted instrument change request sheet. Deleted section 5.4, 7.2 Changed 7.18to maintenance office Changed 12.4 to Pfizer	09/08/2001
Rev 4	<ul style="list-style-type: none"><li>➤ Revised to clarify scope of calibration and include definition of non-critical process instrumentation.</li><li>➤ Sec 7.2 Definition of Non-Critical Instrumentation included.</li><li>➤ Report overdue calibrations to senior management. (Section 6.2)</li><li>➤ Reference SOP No. ENG-097 (Section 8.2)</li><li>➤ Reference SOP No. 6.0715 (Section 8.14)</li><li>➤ Revise Section 11.6 to read "Documentation rules as per SOP 6.0706 to be followed."</li><li>➤ Pfizer Corporate Quality Safety and Environmental Assessment changed to Pfizer Corporate Quality Assurance requirements. (Section 13.4)</li><li>➤ Revision of Appendix 1 and Appendix 2.</li></ul>	

**FOR INFORMATION**

SOPSTATUS: Effective

EFFECTIVE DATE: 29/08/2002 11:25:00 AM

Template Plug-In Version 2.2

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**1. PURPOSE:**

To outline the responsibility and procedure for carrying out periodic calibration on all critical instruments used for the manufacture, processing, packaging or holding of pharmaceutical products and or drug substances.

**2. SCOPE:**

This SOP applies to all critical instruments used for the manufacturer of pharmaceutical products and or drug substances. It does not cover non-critical instruments. Laboratory measurement analytical equipment is covered by other procedures.

**3. ORGANISATIONAL UNITS EFFECTED:**

All Departments where measurement and control equipment is used.

**4. SAFETY:**

Administration procedure only.

**5. REFERENCE DOCUMENTATION**

Failure Investigation – SOP 6.0715

**6. RESPONSIBILITY:**

6.1 Area Managers, Supervisors and FLM's are responsible for:

- a) Ensuring proper storage of measurement equipment when not in use and adequate protection from damage when in use.
- b) Ensuring that back up equipment is available, while items are removed for calibration.
- c) Suspending use of and notifying the Maintenance Department of any instrument that indicates an expired due date for calibration.
- d) Notifying the Maintenance Department of any malfunction of measurement equipment.
- e) Ensuring prompt delivery to the Maintenance Department of equipment due for recalibration.

**FOR INFORMATION**

- 6.2 The Maintenance Department is responsible for:
- a) Co-ordinating any maintenance or re-calibration that may affect the functioning of the equipment or process.
  - b) Communicating any instrument non-conformance to Quality Assurance (QA). Notification will be in the form of an Out of Tolerance Report (Ref. Appendix 1). A copy of such notification will be kept in the Maintenance office.
  - c) Retaining complete calibration history records for all items entered into the calibration programme.
  - d) Monthly reporting of overdue calibrations to senior management including:
    - Quality Operations Director
    - Manufacturing Manager
    - Engineering Manager.
  - e) On a weekly basis, calibrations due for the following week should be sent to the relevant supervisors in the following departments, Manufacturing, Tech-Services, Maintenance and Quality Control.
  - f) QA is responsible for:
    - Reviewing and approving changes to calibration frequencies (Ref. Appendix 2).
    - Reviewing and assessing the impact of any out of tolerance calibration results on product quality and determining investigation requirements.

**FOR INFORMATION**

- 6.3 It is the responsibility of anyone installing or moving measurement equipment to tag this equipment "Do Not Use".

## 7. DEFINITIONS:

- 7.1 Critical Instruments: Devices and Instruments used directly to manufacture, process, package and/or hold pharmaceutical products or drug substances.
- 7.2 Non-critical Instruments: Devices and instruments used for indication purposes only and which have no control function or process impact.
- 7.3 Accuracy: The degree of conformance of a measurement to a standard or true value.
- 7.4 Calibration: A comparison of equipment with a known standard of higher accuracy to check, detect, adjust, rectify and document the accuracy of the equipment being compared.
- 7.5 Precision: The degree of refinement of a measurement and its consistency or reproducibility.
- 7.6 Measurement Equipment: All devices or instruments used to measure, gauge, inspect or examine items to determine compliance with specifications or to determine specifications. It also includes devices, gauges or instruments that have been reviewed and deemed critical to the control of a process.

- 7.7 Reference Standard: (primary standard): These are the standards of the highest accuracy order in a calibration system from which the basic accuracy values for the system are established.
- 7.8 Calibration Standard: (Working standard): This is designated measuring equipment used in a calibration system as a medium for transferring the basic value of reference standards to process measuring and test equipment. This is also referred to as Calibration Equipment or Transfer Standard.
- 7.9 Consensus Standard: An artefact or process that is used as a de facto standard by agreement of the QA Department.

## 8. PROCEDURE :

- 8.1 Before the selection and purchase of measurement equipment, the application, (tolerance, stability, range, resolution and environmental conditions) and safety requirements shall be defined. Measurement equipment shall then be selected which meets or exceeds this definition.
- 8.2 The Instrument Calibration Sheet generated on the Compucal system (Ref. SOP No. ENG-097) and the relevant Standard Operating Procedure will detail items to be checked regarding individual pieces of equipment. In addition, an external calibration sheet will be used for equipment that is calibrated by external contractors.
- 8.3 All measurement equipment will be calibrated according to the relevant procedures.
- 8.4 Calibrations shall not be performed unless environmental conditions are suitable for both the measurement equipment and the calibration standard used.
- 8.5 General Procedures exist for calibrating each type of instrument (e.g. temperature, pressure). Specific procedures are written for certain pieces of equipment due to the complexity of the equipment. Where a specific procedure exists, it takes precedence over a general Procedure.
- 8.6 Suitable environmental conditions, if applicable, shall be specified in the individual calibration procedures.
- 8.7 New or moved equipment will be tagged "Do Not Use" until it is calibrated.
- 8.8 Instruments will be calibrated over their full range.
- 8.9 Where an instrument is connected to a BMS or PLC input the instrument will be calibrated over 5% to 95% of its span.
- 8.10 Adjustment to the schedule will be based on the calibration history for each item.
- 8.11 When calibrating instruments on-site or removing them for calibration elsewhere, the appropriate safety procedures as specified in the relevant SOP must be followed.
- 8.12 All efforts should be made to keep instruments as accurate as possible. Thus instruments should still be re-adjusted even if within tolerance if it is noted that they are approaching the limits of this tolerance.
- 8.13 Measurement equipment will be re-calibrated if dropped, jarred or damaged. Stationary measurement equipment, particularly scales and balances will be re-calibrated after movement.

- 8.14 If an instrument is found to be out of tolerance, an Out of Tolerance Report will be raised by engineering and sent to QA where a decision will be made whether a Notice of Event (NOE) Ref. SOP No. 6.0715 will have to be raised.
- 8.15 If the out of tolerance cannot be corrected a "Do Not Use" label must be placed on the equipment until it is repaired or replaced. If the instrument is being used to control other equipment or gather data from other equipment, QA approval must be obtained to continue using the equipment.
- 8.16 A calibration label will be attached to each item calibrated see Section 11.
- 8.17 Calibration certificates will be filed in the Maintenance office.
- 8.18 Where a record of the accuracy of an individual item is reported via a calibration report or certificate, this document will be attached to the calibration sheet. If this is impractical the calibration sheet will reference the report or certificate.
- 8.19 Where a Notice of Event (Ref. SOP No. 6.0715) is generated, the calibration sheet will reference the report.
- 8.20 All calibrations must be completed on or before calibration due date.
- 8.21 If an instrument cannot be calibrated by its due date, the FEM or Area Manager must be informed.
- 8.22 If an instrument is to be used beyond its calibration due date, written permission is required from the QA Director or designee.
- 8.23 Any equipment that has been repaired must be re-calibrated before being returned to service.
9. CALIBRATION INTERVALS:
- 9.1 The purpose of the schedule is to indicate when calibration of measurement equipment is due.
- 9.2 Calibration intervals will be specified in terms of time.
- 9.3 The next due date will be calculated from the date done. e.g. an instrument calibrated on 2/1 1/96 with a 6 month calibration interval will have a next due date of 2/5/97.
- 9.4 Calibration intervals will be based on manufacturers' recommendations, stability of the instrument, purpose and accuracy or historical calibration data for similar instruments.
- 9.5 New or moved instruments will be tagged "Do Not Use" until calibrated.
- 9.6 If the equipment remains within required accuracy for four successive calibrations, the calibration interval may be lengthened as determined by the Maintenance Department.
- 9.7 If the equipment requires adjustments, the calibration interval should be shortened as determined by the Maintenance Department.
- 9.8 Any change to the calibration interval will be by approval from QA via an instrument calibration interval change request sheet. Ref Appendix 2

**10. SELECTION OF CALIBRATION STANDARDS:**

- 10.1 Standards used for calibrating measurement equipment will have the capability for accuracy, stability and range needed for their intended use.
- 10.2 Calibration Standards used in calibrating measurement equipment will be:
- a) Traceable to the National Bureau of Standards (U. S. A), the National Physical Laboratory (U. K.) or equivalent standards.
  - b) Derived from accepted values of National Physical Constants.
  - c) Supported by certificates, reports or data sheets indicating date and other conditions by which the results furnished were obtained.
- 10.3 Calibration standards used will have an accuracy of at least 4 times the accuracy of the instrument under test. Where it is not possible to achieve this, a less accurate instrument may be used provided all deviations are thoroughly documented and justified on the calibration record.
- 10.4 Standards chosen on the basis of manufacturers' specifications only shall be subjected to close surveillance until a data base in relation to stability is established as a result of successive calibrations.
- 10.5 All calibration standards used in the calibration system will be supported by certificates, reports or data sheets indicating the date and conditions in which the results were obtained.
- 10.6 A calibration standard, when not in use shall be stored in a manner which prevents unauthorised adjustment. In addition, the storage environment shall meet the calibration standard storage requirement.

**11. USE OF CALIBRATION LABELS:**

- 11.1 The Maintenance Department is responsible for the accuracy of the information displayed on the calibration label.
- 11.2 Equipment without current labels should not be used for any purpose and should be reported to the Maintenance Department by the identifier.
- 11.3 When the size or operational characteristics of the equipment make the use of standard calibration labels impractical, a smaller label will be attached to the equipment.
- 11.4 Old calibration labels are to be removed on application of the new calibration labels. Under no circumstances are new calibration labels to be placed over old calibration labels.
- 11.5 Indelible pens to be used for writing on calibration labels at all times.
- 11.6 Documentation rules as per SOP No. 6.0706 to be followed.
- 11.7 The calibration label should have the following information: Instrument tag number, date of calibration (dd/mm/yy), signature of person performing calibration and date next calibration is due (dd/mm/yy).



**FOR INFORMATION**

## 12. MAINTENANCE OF CALIBRATION RECORDS:

12.1 The purpose of maintaining calibration records is to:

- a) Be assured that calibration schedules are maintained.
- b) To provide a calibration history in relation to equipment stability which may be used as a database for the adjustment of calibration intervals.
- c) To provide sufficient information to set up a replacement instrument if necessary.

12.2 A calibration record must be maintained for each critical instrument. The record should include the following information as applicable: Tag No, Description, Manufacturer, Model, Serial No., Location, Dip-switch setting, Limit settings, Controller settings, Configuration programme. Calibration frequency, Calibration procedure/instructions.

## 13. SELECTION OF CONTRACTING CALIBRATION SERVICES:

13.1 The general objective to be achieved when using contract calibration services is to determine that the calibration service is capable of performing the work to the satisfaction of the company.

13.2 It is the responsibility of the Maintenance Department to ensure that the contracting calibration service is suitable for the requirement.

13.3 Contract calibration services shall have procedures in place which assures the accuracy and traceability of their calibration standards.

13.4 Calibration contractors shall be audited as per Pfizer Corporate Quality Assurance requirements to assure adherence to this document as well as their own internal procedures.

## 14. OUT OF TOLERANCE ACTION:

14.1 The intervals of calibration are chosen to ensure instruments will still be in tolerance when next checked although they may be approaching the limits of that tolerance. If an instrument is found to be out of tolerance when calibrated the cause must be identified. Due to the effect an out of tolerance instrument may have on the quality and effectiveness of production, QA must be **notified** by an out of tolerance report and a Notice of Event submitted if required by QA as per SOP 6.0715 Failure Investigation.

14.2 The Out of tolerance report is intended as a **notification** to the QA Department that a problem has been noted. It should give QA all available information to enable them to decide if product quality has been affected and if further investigation is required.

- 14.3 Where an out of tolerance occurs and the cause is not immediately apparent, the instrument must be replaced, if it cannot be immediately rectified, written QA approval is required to continue using it.
- 14.4 Where the cause of an out of tolerance is apparent and correctable, the instrument may be recalibrated and returned to service. Impact on product quality is assessed by QA. Ref. Appendix 1, Section E.

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APPENDIX I

<b>OUT OF TOLERANCE REPORT</b>		Number
A	Device Type: _____	Model/Type: _____
	Tag No: _____	Serial No: _____
B	Device Function: _____	
C	Process Involved: _____	
	Action Taken: _____	
	<b>FOR INFORMATION</b>	
Signature (Maintenance Department): _____		Date: / /
D	QA Person Notified: _____	By: _____ Date: / /
E	QA Evaluation:	
	Notice Of Event required	MAINT      PROD      OTHER _____ (Please specify)
Signature (QA): _____		Y/N      Y/N      Y/N Date: / /

Maintenance: Complete section A-D, copy and send original to QA  
 QA: Complete section E, verify section D, send original to Maintenance and retain copy

Date original received by QA: / / Date final copy received by Maintenance: / /

Appendix 2

**INSTRUMENT CALIBRATION INTERVAL CHANGE REQUEST**

**TAG No:**

**MAKE:**

**MODEL:**

**SERIAL No:**

LAST CALIBRATION DATES:

1. / /
2. / /
3. / /
4. / /

ADJUSTMENT REQUIRED:

YES  NO

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**CHANGE INTERVAL:**

FROM: DAYS: TO: DAYS:

**REQUESTED BY:** \_\_\_\_\_

MAINTENANCE DEPARTMENT DATE: / /

**APPROVED BY:** \_\_\_\_\_

QA DEPARTMENT DATE: / /

**COMMENTS:**

\_\_\_\_\_

**STANDARD OPERATING PROCEDURE**



<b>SOP NUMBER:</b> 6.0362	<b>SOP VERSION:</b> 2.0
<b>EFFECTIVE DATE:</b> 29/08/2002 09:45:00 AM	
<b>SOP TITLE:</b> OPERATION OF THE PEMAC MAINTENANCE SYSTEM	

**SIGNATURE INFORMATION**

	<b>SIGNATURE</b>	<b>DEPARTMENT</b>	<b>DATE</b>
Originated By:	Grace Healy	Maintenance Engineering	20/08/2002 02: 18:19 pm
Reviewed By:	John Toner	Maintenance Engineering	20/08/2002 03: 13:31 pm
Reviewed By:	Mary Casey	Environmental Health & Safety	21/08/2002 09:43:20 am
Approved By Quality:	Susan Neenan	Quality Assurance	21/08/2002 11: 15:42 am

*Maintenance Engineering  
Purchasing  
IN 29.8.2002*

**FOR INFORMATION**

SOP NUMBER: 6.0362

SOP VERSION: 2.0

SOP TITLE: OPERATION OF THE PEMAC MAINTENANCE SYSTEM

NO.	REVISION DETAILS	EFFECTIVE DATE
ORIG.	Procedure written to replace ENG-063. Updated for PQ0502. ENG-063 to be voided.	11.06.98
Rev. 1	<p>3 Year review - revised to DMS format</p> <p>Sec.2 Include ref. to non critical equipment</p> <p>Sec. 3 Added relevant depts.</p> <p>Sec. 7: Include exceptions to requirements to change control!</p> <p>General: Change ref. from Coordinator to Superintendent &amp; include ref. to maintenance archive Change ref. from Production Mgr. To Engineering &amp; Maintenance Mgr. Change day by which routines are to be issued to Monday Change ref. From Validation manager to Tech Services Manager Include ref. to Engineering Manager. QC dept included in <b>Organisational</b> Units. Procedure section : Point about 'Do Not Use' tags removed Change Control: Altered second point to state that change control is not required for addition of new equipment, new routines for existing equipment and minor text changes for existing plant. Procedure: Included comment <b>that</b> PM frequencies require change control. (6<sup>th</sup> bullet point) Sec 7.4 Included Work Order circulation list. <b>end.</b></p>	

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SOP STATUS: Effective

EFFECTIVE DATE: 29/08/2002 09:45:00 AM

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page 2 of 5

**1. PURPOSE:**

To describe the operation of the PEMAC Planned Maintenance System.

**2. SCOPE:**

This procedure covers maintenance on critical plant equipment only. Critical equipment is equipment used directly to manufacture, process, package and/or hold pharmaceutical products and/or drug substances. Laboratory analytical equipment is not covered by this procedure.

(Non critical equipment is also maintained under the auspice-s of PEMAC)

**3. ORGANISATIONALUNITS :**

Maintenance Engineering  
Production  
Project Engineering  
QA  
QC dept.

**4. SAFETY:**

Administrative procedure only.

**5. REFERENCE \ DOCUMENTATION:**

The following documentation is stored in the Maintenance office \ Maintenance Archive.  
Planned. Unplanned and Scheduled Work Orders.  
Direct History Sheets.

**6. EQUIPMENT**

(N/A)

**FOR INFORMATION**

**7. PROCEDURE**

**7.1 RESPONSIBILITY:**

- It is the responsibility of the Engineering \ Maintenance Manager to ensure that plant maintenance is performed in accordance with this procedure.
- It is the responsibility of the QA department to review and approve preventative maintenance instructions, including preventative maintenance frequencies.
- It is the responsibility of the Production Department to suspend use of all equipment that is suspected of not functioning correctly or has been dropped, jarred or otherwise damaged and to report such equipment to the Maintenance Department.
- It is the responsibility of the Department installing new equipment or moving existing equipment to tag this equipment as "Do Not Use" and to inform the Maintenance Department of new or moved equipment.
- It is the responsibility of any person specifying or ordering new equipment to submit for approval, applications and specifications for equipment to the Maintenance Department.

## 7.2 CHANGE CONTROL:

- Any changes to PEMAC planned maintenance system will be via change control.
- This excludes addition of new equipment. new routines for existing equipment and minor text changes for existing plant.

## FOR INFORMATION

## 7.3 NEW EQUIPMENT:

- Engineering will be notified by the Originator of any new equipment arriving on site.
- Engineering will assign the equipment a PEMAC number.
- The originator will note this number on the delivery documentation and apply a sticker/sign to the equipment stating "Do Not Use".

## 7.4 PROCEDURE:

- Prior to the selection and purchase of critical equipment, the application, specification and safety requirements shall be defined. Critical equipment is defined as equipment used directly to manufacture, process package and/or hold Pharmaceutical and Consumer Healthcare products.
- Any person specifying or ordering new equipment must submit for approval, applications and specifications for the equipment to the Maintenance Department.
- Individual Preventative maintenance Instructions exist for each type of equipment.
- Equipment will be identified, checked and adjusted prior to use.
- Maintenance frequencies are based on manufacturer's recommended intervals and/or historical maintenance data for similar equipment.
- Maintenance intervals may be modified when the results of previous experience provide proof that the equipment will continue to operate satisfactorily throughout the new interval. Modifications to PM frequencies are done through change control.
- Planned Maintenance Work Orders are generated by the Maintenance Superintendent or designated deputy from the PEMAC system by Monday of the week for the following week and issued to the relevant personnel who carry out the tasks on the work order.
- When the tasks are completed and recorded the Planned Work Order Form, it is checked and signed off by the Maintenance Superintendent.
- If a planned or scheduled work order highlights a defect or problem area, a corrective action must be taken
- If the work cannot be completed at the time of the check, the Corrective Action takes the form of an Unplanned Work Order. The Maintenance Superintendent or designee will issue an Unplanned Work Order from the PEMAC system. This will reference the Planned Work Order number, and likewise the Planned Work Order will reference the Unplanned Work Order number.
- If equipment is found to be faulty or operating outside of validated conditions, a Notice of Event will be completed if required by QA and approval from QA obtained to continue using the equipment.
- When completed the Unplanned Work Order is checked and signed off by the Maintenance Superintendent or designee. The completed Unplanned Work Order is filed with the original Planned Work Order.
- If any work is performed on Critical Plant Items between planned checks that is not covered by an Unplanned Work Order then a Direct History Log must be filled out.
- The Maintenance Superintendent or designee enters the details of the Work Orders into the PEMAC system weekly.
- Completed Work Order sheets are filed in the Maintenance office or archive by week number.



SOP NUMBER: 6.0362  
SOP VERSION: 2.0  
SOP TITLE: OPERATION OF THE PEMAC MAINTENANCE SYSTEM

- When equipment is not available. The sheet will be signed and returned indicating this.
- A list of all outstanding work orders will be generated once a month to the following people on site:
  - Site Team Leader
  - Engineering Manager
  - Quality Director
  - Production Manager
  - Maintenance Superintendent

8 APPENDIX  
N/A

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