STANDARD OPERATING PROCEDURE

SOPNUMBER: 6.1021	SOPVERSION: 3.0
EFFECTIVEDATE: 30/09/2003 11:35:00 AM	
SOP TITLE: DISPOSAL OF WASTE BOVINE MATERIAL,	

SIGNATURE INFORMATION

	SIGNATURE	DEPARTMENT	DATE
Originated By:	Vicky Bow	Environmental Health & Safety	11/09/2003 08:41:53 am
Reviewed By:	Carmel Crowley	Manufacturing	1 l/09/2003 09:24:35 am
Reviewed By:	Tony Carter	Environmental Health & Safety	1 l/09/2003 06:08:58 pm
Approved By Quality:	Ann Whelan	Quality Assurance	12/09/2003 11:42:38 am

Suite #1
Suite #3
Environmental Health & Safety
Entry F.H 30/09/03

FOR INFORMATION

NO.	REVISION DETAILS	EFFECTIVE DATE
ORIGINAL		22/07/96
Revision 1	Updated to reflect recent legislative changes, to change responsibilities within SOP and update packaging requirements. Updated circulation list.	02.04.99
Revision 2	Updated to reflect current disposal routes. All references to Warner Lambert amended to Pfizer. Section 4 revised to included further information on Waste Bovine Material on-site. Section 5 updated to include references to safety shoes and SOP 6.0205. Section 6 revised in-line with current practices and new disposal routes for animal healthcare waste. Appendices 1 & 2 removed as are no longer applicable.	29.08.02
Revision 3	Title changed from Animal Healthcare Waste to Waste Bovine Material. The following changes were made: Section 3.0 revised to update responsibilities. Section 4.0 terms of reference deleted and replaced with Pfizer Waste Designations. Section 5.0 updated to include wheelie bin weight restrictions. Section 6.0 revised to remove all references to cultures and stocks of infectious agents and sharps, to include wastes classified as waste bovine material and to detail handling and disposal for each waste. All references to 'Designated Member of Maintenance/Engineering Department' amended to 'Waste Handlers'. Section 7 added to include reference to Waste Management Policy SOP 6.1025 Reference to SOP 6.0911 included. Reference to SOP 6.1002 removed. Official Copy List deleted and Circulation List amended.	

Original to be filed in QA

1.0 PURPOSE

To detail the requirements for the disposal of Waste Bovine Material.

2.0 SCOPE

Waste bovine material results from the production of Biological Products on site; therefore this procedure applies to all areas where biological product manufacturing takes place.

3.0 REFERENCES

All waste streams detailed in this SOP are classified in accordance with the Pfizer Corporate Waste Management Guideline 19.

The collection of Waste Bovine Material, the treatment of the waste off-site and associated documentation is detailed in the Waste Management Policy SOP 6.1025.

4.0 RESPONSIBILITIES

It is the responsibility of the EHS Department to correctly categorise all bovine related wastes generated on site and to ensure that they are disposed of in accordance with the site IPC Licence, relevant waste legislation and the Corporate EHS Waste Management Guideline 19.

It is the responsibility of the Production FLM to ensure that all wastes generated are disposed of in accordance with this SOP and that suitable equipment and areas for waste storage are available to ensure correct disposal.

It is the responsibility of the Production FLM to ensure that all waste is labelled correctly.

5.0 PFIZER WASTE DESIGNATION

In line with the Pfizer Corporate EHS Waste Management Guideline 19, all waste bovine material is classified as a 'Special Waste'.
A definition for Pfizer Special Waste 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.

6.0 SAFETY

Wear the appropriate personal protective equipment including gloves and safety shoes when dealing with waste bovine material

Report all accidents/near misses to your FLM or supervisor and complete the relevant forms as soon as practicable in accordance with SOP 6.0205.

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

Ensure that all 400L Wheelie Bins are only filled to the level/weight designated in this SOP in order to control the 100Kg per wheelie bin weight restriction, imposed by the waste management contractor.

7.0 PROCEDURE

7.1 Waste Bovine Material

The following wastes are classified as waste bovine material:

- Bovine Lung
- Bovine Lung Packaging
- PLE Waste
- Non-Aqueous Protein Waste
- Waste Bovine Plasma and Serum

7.2 Bovine Lung and Associated Bovine Lung Packaging

Rejected bovine lung and any associated packaging resulting from bovine **lung is** placed in a 400L wheelie bin as it arises. These wheelie bins are then stored in the -20°C waste freezer prior to collection by the waste contractor.

7.3 Purified Lung Extract Waste

PLE Waste is placed into a 400L Wheelie Bin as the waste arises during the production process. These bins are then brought to the -20°C waste freezer for storage prior to collection by the waste contractor.

In the case of PLE Waste it is important that the 400L wheelie bin should only be filled to ¼ full in order to adhere to the 100Kg weight restriction per bin.

7.4 Non-Aqueous Protein Waste

As is arises, non-aqueous protein waste is placed in labelled white plasma/serum buckets. These buckets are then placed in the designated wheelie bins outside the bulk manufacturing area, by production personnel.

It is the responsibility of the production personnel to ensure that the100kg weight restriction is adhered to when placing the buckets in the wheelie bins.

7.5 Bovine Serum/Bovine Plasma

As bovine serum and bovine plasma is rejected at Eirfreeze, this waste is delivered on site, placed into 200L wheelie bins by the waste handlers and stored in the -20°C waste freezer prior to collection by the waste contractor.

7.6 Additional Wastes

Filters and associated wastes that have come in contact with Biological Products are placed in Wheelie Bins located outside the Bulk Manufacturing Area.

8.0 WASTE COLLECTION AND DISPOSAL

Waste bovine material in the designated 400L wheelie bin is collected by an approved waste contractor upon request by the EHS Department. The waste is treated at the contractor facility to render it non-infectious and is disposed to landfill at an approved facility.

Documentation and records associated with the shipment of this waste off-site is detailed in the Waste Policy SOP 6.1025.

STANDARD OPERATING PROCEDURE

SOP NUMBER:	SOP VERSION:
6.1023	5 . 0
EFFECTIVE DATE: 01/10/2003 02:45:00 PM	
SOP TITLE: DISPOSAL OF IN PROCESS AND FINISHED PRODUCT WASTE	

SIGNATURE INFORMATION

	SIGNATURE	DEPARTMENT	DATE
Originated By:	Vicky Bow	Environmental Health & Safety	10/09/2003 11:16:33 am
Reviewed By:	Carmel Crowley	Manufacturing	10/09/2003 04:42:43 pm
Reviewed By:	Tony Carter	Environmental Health & Safety	10/09/2003 06:02:54 pm
Approved By Quality:	Ann Whelan	Quality Assurance	1 l/09/2003 10:48:13 am

Suite #1
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Inspection
Entry 7-H 01/10/03

FOR INFORMATION

No.	Revision Details	Effective Date
ORIGINAL		25/10/96
Revision 1	Procedure updated for Cerebyx	03102197
Revision 2	Procedure updated to reflect recent legislative changes in waste classification.	04/09/97
Revision 3	Procedure updated for CI1025	27/07/99
Revision 4	Updated to correct revision no.	26/08/99
Revision 5	Updated Section 5.2 to include UK-292,663 Fluconazole Prodrug. Other minor text changes	1011112000
Revision 6	Updated to include Azithromycin for injection 500mg/vial (1 00mg/ml When Reconstituted) and Azithromycin Powder for Solution for Infusion 500 mg/vial (100mg/ml When Reconstituted)	1 l/06/2001
Revision 7	Updated to include Voriconazole for Infusion 10mg/ml when reconstituted, 200mg/Vial Remove reference to SOP 6.0901 'Hazard Awareness and Reporting at Warner Lambert' (Section 3.0) as this SOP has been discontinued	30/11/2001
Revision 8	Title changed to Disposal of In Process and Finished Product Waste. Complete rewrite to include the Pfizer waste designations of Special and Non-Special Waste. Waste Streams and associated disposal routes updated for currency. References to the following SOP's included: 6.1004 Disposal of Municipal Waste at Pfizer 6.1021 Disposal of Waste Bovine Material 6.1025 Waste Management Policy Official Copy List Deleted.	

Original to be filed in QA

FOR INFORMATION

1.0 PURPOSE

The purpose of this procedure is to define the waste stream handling, collection and treatment/ disposal methods for in process and finished product waste and any waste formed as a result of the production processes on site.

2.0 ORGANISATIONAL UNITS AFFECTED

- Bulk Manufacturing
- Manufacturing Suite 1
- Manufacturing Suite 3
- Manufacturing Inspection and Packaging
- QC
- QCI
- Materials Management
- Maintenance/Engineering Department – Waste Handlers
- EHS Department

3.0 RESPONSIBILITIES

It is the responsibility of the EHS Department to classify all waste streams generated on site to ensure they are adequately disposed of in accordance with applicable legislation, the site IPC Licence and the Pfizer Corporate Waste Management Guideline 19.

It is the responsibility of the EHS Department to schedule the shipment of all 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 Departmental Managers to ensure that waste is segregated and disposed of in accordance with the disposal routes detailed in this SOP.

4.0 SAFETY

Report all accidents/near misses immediately to a Supervisor/Manager and compile an Accident/Near Miss Report as soon as possible as per SOP 6.0205.

Ensure you are aware of the safety requirements for all products. Consult MSDS before working with pharmaceutical materials.

Handle all Special Waste with care using the appropriate safety equipment, refer to SOP 6.093 1. Wear respirator with combination filter if exposed to product waste in powder form.

Label all waste appropriately and clearly.

Ensure correct manual handling technique is used. See SOP 6.0911.

Leaking containers should be identified and notified to the relevant Departmental Manager immediately. In the event of a spillage consult SOP 6.1007.

5.0 PFIZER WASTE DESIGNATION

In line with the Pfizer Corporate EHS Waste Management Guideline 19, all waste streams on site are classified as either 'Special Waste' or 'Non-Special Waste'.
A definition for Pfizer Special and Non-Special Waste is detailed below:

Special Waste is any wastestream comprised of biological, radiocative 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 as non-special if the total wastestream volume is less than 100 kg 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.

6.0 PROCEDURE

6.1 Production of Biological Products

Biological products include the following intermediates and products:

Intermediates

- Prothrombin
- Purified Lung Extract
- Fibrinolysin
- BPT Glycerine 50:50

Products

- Thrombin (liquid)
- Thrombostat (freeze dried)
- Fibrinuclease Powder
- Elase

The following waste streams arise from the production of these intermediates/products. All biological product related waste is considered **Special Waste** and must be disposed of in accordance with the site IPC Licence and the Pfizer Corporate Waste Management Guideline.

6.1.1 *Biological Solid Waste*

All solid waste resulting from the production of these intermediates and products must be labelled and placed into the appropriate biological waste bin. Solid waste includes items such as used filters and waste garb. This waste is disposed of to the designated 400L wheelie bins and stored in the -20°C waste freezer prior to collection for treatment of site by an approved waste contractor.

Waste bovine material including bovine lung, plasma and serum, PLE waste and non-aqueous protein resulting from the production of these intermediates/products is detailed in SOP 6.1021 Disposal of Waste Bovine Material.

6.1.2 Biological Liquid Waste

All intermediate and product liquid waste may go to drain. In the event of a batch failure it is the responsibility of the FLM to inform the Environmental Officer, who will arrange for the waste liquid to be transferred to a 200L drum. This waste will then be stored in the external waste cabinets prior to disposal off-site by incineration at an approved facility.

6.1.3 Waste/Reject Biological Vials

All biological product waste vials should be placed in the waste vial bin along with pharmaceutical vials. These vials are collected by the waste handlers at designated collection points and brought to the trash room. The waste handlers then transfer the waste vials into labelled 200L drums. These drums are then stored in the external waste cabinets prior to disposal off-site by incineration at an approved facility.

Rejected batches of biological product vials are placed in 200L drums for disposal by warehouse personnel. These drums are then stored in the external waste cabinets prior to disposal off site.

6.2 Production of Pharmaceutical Products

Pharmaceutical products on site include:

- Azithromycin for Injection 500mg/vial
- Cerebyx 150mg/vial, 750mg/vial
- Ketalar 10mg/ml, 50mg/ml, 100mg/ml
- Ketanest S 5mg/ml, 25mg/ml
- Phosphenytoin 750mg/vial
- Fosfluconazole 100mg/vial, 200mg/vial, 400mg/vial
- Voriconazole for Infusion 200mg/vial

The following waste streams arise from the production of these products. All pharmaceutical product related waste is considered Special Waste and must be disposed of in accordance with the site IPC Licence and the Pfizer Corporate Waste Management Guideline.

6.2.1 Solid Pharmaceutical Contact Waste

All solid pharmaceutical contact waste arising from the production of the products detailed above must be suitably labelled and placed in the appropriate bin for incineration. Solid waste includes used filters, used mask cartridges, spent vacuum HEPA filters, waste garb etc. This waste is placed in 200L Drums and sent to an approved facility for incineration.

Large HEPA filters from the dispensary are placed in FIBC Bags and sent off site for incineration at an approved facility.

6.2.2 Pharmaceutical Liquid Waste

All liquid product waste must be collected for incineration in suitably labelled containers. In the event of a batch failure it is the responsibility of the Production FLM to ensure that the liquid product waste is placed in a 200L Drum for disposal by incineration. These drums are stored in the external waste cabinets in preparation for disposal.

6.2.3 Waste Pharmaceutical Vials

All waste pharmaceutical product vials should be placed in the waste vial bin. These vials are collected by the waste handlers at designated collection points and brought to the trash room. The waste handlers then transfer the waste vials into labelled 200L drums. These drums are then stored in the external waste cabinets prior to disposal off-site by incineration at an approved facility.

Rejected batches of pharmaceutical product vials are placed in labelled 200L drums for disposal by warehouse personnel. These drums are then stored in the external waste cabinets prior to disposal off site.

6.3 Wastes Associated with Production Activities

Additional Special Wastes arise on site as a result of production activities. These wastestreams are detailed below.

6.3.1 *Chloroform Bovine Waste*

Chloroform bovine waste results from the production of Fibrinolysin in the Bulk Manufacturing Area. This waste is pumped into a labelled 200L drum in the external bunded store outside the Bulk Manufacturing Area. These drums are collected by the waste handlers and placed in the external waste cabinets in the waste area prior to disposal off site by incineration at an approved facility.

6.3.2 Carbon Contaminated with Chloroform

This waste results from a change in the carbon absorbent filter (associated with the production of Fibrinolysin) located on the mezzanine. Waste carbon is placed into labelled 200L drums by an external contractor carrying out the carbon change. These drums are transported **to** the external waste cabinets by the waste handlers prior to disposal off site by incineration at a approved facility.

6.3.3 Klercide A and Klercide B Waste

All waste klericide resulting from production should be placed in labelled ***plastic*** 200L drums for disposal. Plastic drums must be used as klericide is corrosive and will corrode steel drums. This waste is collected by the waste handlers and placed in the external waste cabinets in the waste area prior to disposal off site by incineration at a licenced facility.

6.4 Pharmaceutical Raw Material and Other Excipients

Surplus and reject pharmaceutical raw materials and production excipients are also considered Special Wastes. These wastes are disposed off site by incineration at an approved licenced facility. These wastes originate from the Dispensary and the Warehouse and are stored (in their original containers) in the external waste cabinets prior to disposal.

The Materials Manager will notify the Environmental Officer of reject/surplus pharmaceutical raw materials and excipients as they arise and the Environmental Officer will organise the disposal of these wastes, by incineration.

6.5 Contaminated Raw Material Packaging

All packaging that has been in contact with products produced on site is considered a Special waste and must be sent off site for incineration. This waste originates in the Dispensary and is placed in suitable drums by the waste handlers. This waste is stored in the external waste cabinets prior to disposal off-site.

6.6 Non-Special Waste

Non-special waste resulting from production related activites includes non-contaminated packaging, fibre kegs and general waste. This waste is disposed of to the site compactor.

Rejected non-product contact glass vials should be placed in 200L drums for disposal off site by recycling.

7.0 WASTE SHIPMENT OFF SITE

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

STANDARD OPERATING PROCEDURE

SOP NUMBER:	SOP VERSION:
6.1024	2.0
EFFECTIVE DATE: 15/11/2004 02:00:00 PM	
SOP TITLE: DISPOSAL OF MAINTENANCE AND PROJECT RELATED WASTE	

SIGNATURE INFORMATION

	SIGNATURE	DEPARTMENT	DATE
Originated By:	Vicky Bow	Environmental Health & Safety	10/09/2004 04:46:40 pm
Reviewed By:	John Toner	Maintenance Engineering	27/09/2004 05:42:00 pm
Reviewed **By:**	Tony Carter	Environmental Health & Safety	06/10/2004 09:25:14 am
Approved By Quality:	Susan Neenan	Quality Assurance	06/10/2004 10:57:30 am

Maintenance.

EHS.

Entry: 15/11/04.

FOR INFORMATION

Version	Revision Details	Effective Date
1.0	Original - Written to document the waste streams produced from maintenance activities and project related operations on site. This SOP details the Pfizer Waste Designations of 'Special Waste' and 'Non-Special' Waste in line with the Pfizer Corporate EHS Waste Management Guideline9. This SOP also makes reference to the Waste Management Policy SOP 6.1025 which details the requirements and associated documentation for shipping waste off-site.	26/09/03
2.0	Sections 7.1.10 and 7.1.11 added to include detail on Asbestos and PCB waste streams. Table in Section 7.3 updated accordingly.	

1.0 PURPOSE

The purpose of this procedure is to define the waste stream handling, collection and treatment/disposal methods for all maintenance related wastes generated on site at Pfizer, Dublin.

2.0 ORGANISATIONAL UNITS AFFECTED

- Maintenance/Engineering Department
- Project Engineering Department
- EHS Department
- IS Department

3.0 REFERENCES

All waste streams detailed in this SOP are classified in accordance with applicable legislation, the site IPC Licence and the Pfizer Corporate EHS Waste Management Guideline 19.

The shipment of all waste off site is detailed in the Waste Management Policy SOP 6.1025.

The Disposal of Municipal waste off site is detailed in SOP 6.1004 – Disposal of Municipal Waste at Pfizer, Dublin.

4.0 RESPONSIBILITIES

It is the responsibility of the EHS Department to classify all wastes generated on site and to ensure that these waste streams are adequately disposed of in accordance with applicable legislation, the Site IPC Licence and the Pfizer Corporate EHS Waste Management Guideline 19.

It is the responsibility of the EHS Department to schedule the collection of all wastes detailed in this SOP.' The requirements and documentation associated with the collection of these wastes is detailed in the Waste Management Policy SOP 6.1025.

It is the responsibility of the Departmental Managers to ensure that all wastes generated are disposed of in accordance with this SOP and that suitable equipment and areas for waste storage are available to ensure correct disposal.

5.0 SAFETY

Waste containers must be properly labelled to indicate the specific types of waste being disposed.

Wear personal protective equipment relevant to the waste you are handling and how well it is packaged. This includes safety glasses, gloves and safety shoes at a minimum. Consult the relevant MSDS before handling.

Ensure you use the correct manual handling technique - follow SOP 6.0911 at all times. Where possible use mechanical aids such as fork trucks, pallet trucks etc. when handling heavy loads.

Report all accidents/near misses immediately to a Supervisor/Manager and complete an Accident/Near Miss Report as soon as possible, in accordance with SOP 6.0205

6.0 PFIZER WASTE DESIGNATION

In line with the Pfizer Corporate EHS Waste Management Guideline 19 all waste streams on site are classified as either 'Special Waste' or 'Non-Special Waste'.
A definition for Pfizer Special and Non-Special Waste 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.

7.0 PROCEDURE

Each of the maintenance and project related waste streams produced on site, where it is produced and how it is handled and stored is detailed below.
Note: Chemical Waste Streams cannot be disposed unless a current MSDS is available for the material.

7.1 Special Waste

The following special waste streams arise on site from maintenance and project related activities:

7.1.1 Fluorescent Tubes

Fluorescent tubes and lamps result from lighting replacements throughout the plant. These tubes should be placed in the designated lamp storage container (coffin) located in the Maintenance/Engineering Plant Room

It is the responsibility of the Environmental Officer to schedule a lamp collection by an external approved contractor when instructed by the Maintenance/Engineering Personnel.

7.1.2 Waste Oil

Waste oil is generated from equipment oil changes and is stored in a 200L waste oil drum in the oil store.

It is the responsibility of the Environmental Officer to schedule a waste oil collection by an external approved contractor when instructed by the Maintenance/Engineering Personnel.

7. I.3 ***Grease***

The Environmental Officer should be informed of any waste grease or waste empty grease containers as they arise. The Environmental Officer will arrange for the grease/containers to be stored in a suitably labelled container in the external waste cabinets and will schedule disposal of the waste off-site.

7.1.4 Glycol ***Waste***

All ethylene glycol waste resulting from the plant chilled water system should be placed in a labelled fixed top 200L steel drum. The Environmental Officer should be notified of this waste as it arises and will arrange for it to be stored in the external waste cabinets in preparation for disposal off-site.

7.1.5 ***Contaminated Resin***

This waste results from a change in the resin associated with the Elga water treatment system. The Environmental Officer should be notified of this waste as it arises and will arrange for it to be placed in labelled 200L drums and stored in the external waste cabinets in preparation for disposal off-site.

7.1.6 ***Paint***

The Environmental Officer should be informed of any waste paint or waste empty paint containers as they arise. The Environmental Officer will arrange for the paint/paint tins to be stored in a suitably labelled container in the external waste cabinets and will schedule disposal of the waste off-site to an approved disposal site.

7.1.7 ***Contaminated Plastic Containers***

Contaminated plastic containers result from boiler dosing chemicals and cooling tower chemical containers. It is the responsibility of the Maintenance/Engineering personnel to inform the Environmental Officer as these containers arise and disposal off site to an approved waste contractor will be scheduled. Empty containers or waste material should be stored in the waste cabinets in preparation for disposal.

7.1.8 Drain and Interceptor Waste

Only an approved external waste contractor can be commissioned to clean out and dispose of drain and interceptor waste. The Environmental Officer should be contacted in advance of any drain cleaning operations to ensure that the correct documentation is available to be singed as per the Waste Management Policy SOP 6.1025.

7.1.9 Refrigerants

It is the responsibility of the Environmental Officer to schedule the disposal of refrigerants or equipment containing refrigerants off site as they arise. The Environmental Officer will ensure that only approved contractors that are licensed to accept refrigerants and refrigerant related waste will be used.

7.1.10 ***Asbestos***

It is the responsibility of the Environmental Officer to schedule the disposal of asbestos waste or equipment containing asbestos off site as required. Only approved waste contractors and waste disposal facilities will be used.

7.1.11 PCS'S

All lighting capacitors and ballasts suspected of containing PCB's must be disposed to the dedicated 200L waste Combi drum in the Electrical Waste Store. The Waste Electrical Store is located in the contractor's compound.

7.2 Non-Special Wastes

The following Non-Special Wastes arise on site as a result of maintenance and project related activities.

7.2. I Batteries

Batteries arise from a variety of sources on site. Batteries should be segregated and placed in the appropriate storage containers as follows:

a) Lead Acid Batteries - these batteries can be identified by the Pb symbol detailed on the battery. These batteries should be stored in the waste battery storage container in the external waste storage area.

b) Nickel Cadmium Batteries - these batteries include household batteries, mobile phone batteries and rechargeable batteries. They can be identified by the NiCd symbol detailed on the battery. These batteries should be disposed to the battery recycling container located in the Maintenance/Engineering Plant Room.

It is the responsibility of the Environmental Officer to schedule a waste battery collection by an approved waste contractor when instructed by a member of the maintenance/engineering department or the waste handlers

7.2.2 Waste Electronic and Electrical Equipment (WEEE)

WEEE is defined as 'equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents' and **is** 'designed for use with a voltage rating not exceeding 1000 Volt for alternating current **and** 1500 Volt for direct current.'

WEEE contains a variety of materials and components, including some that are considered dangerous. Commonly found components include: printed circuit boards, flame retarded plastics, cathode ray tubes, liquid crystal displays, mercury switches, capacitors and resistors. White goods such as computers and computer related equipment, fridges, televisions, toasters and microwaves also fall into this category.

All WEEE should be stored in the dedicated storage container located in the contractor compound.

It is the responsibility of the Environmental Officer to schedule a collection of this waste by an approved waste management contractor upon instruction from a member of the Project Engineering Department or the Maintenance/Engineering Department

7.2.3 Metal Waste

Scrap metal arises from construction and demolition activities and from the dis-investment of equipment on site. This metal is stored on site and then placed in a designated skip.

7.2.4 Construction Waste

As it arises all construction and demolition waste that leaves site will be undertaken by licenced hauliers to licensed disposal facilities.

7.2.5 Canteen Cooking Oil

Waste Canteen Cooking Oil as it arises, is placed in a labelled 200L drum for disposal by the Waste Handlers. This waste is sent off site for incineration at an approved facility.

7.2.6 Municipal Wastes

Additional non-special municipal wastes generated on site are detailed in SOP 6.1004, Disposal of Municipal Waste at Pfizer, Dublin.

7.3 Waste Stream Storage and Disposal Method

The follow table details the storage container and disposal method for each of the waste streams listed above.

Waste Stream	Pfizer Designation	Storage Container	Disposal Method
Fluorescent Lamps	Special	Lamp Coffin	Recycling
Waste Oil	Special	200L Drum	Recovery
Grease	Special	Original Container	Incineration
Glycol	Special	200L Drum	Incineration
Contaminated Resin	Special	200L Drum	Incineration
Paint	Special	200L Drum	Incineration
Contaminated Plastic Containers	Special	Waste Cabinets	Cleaning, shredding and landfill
Drain and Interceptor Waste	Special	Not applicable	Wastewater Treatment
Refrigerants	Special	Original Container/ Equipment	Incineration
Asbestos	Special	Dedicated Storage Container Required	Landfill
PCB's	Special	200L Drum in Waste Electrical Equipment Store	Incineration
Batteries - Lead Acid	Non-Special	Waste Battery Container	Recovery
Batteries -Nickel Cadmium	Non-Special	Recycling Battery Container	Recovery
WEEE	Non-Special	Storage Container in Contractor Compound	Recovery / Recycling
Metal Waste	Non-Special	Metal Skip	Recycling
Construction Waste	Non-Special	Storage container determined as the waste arises	Disposal method determined as the waste arises
Canteen Cooking Oil	Non-Special	200L Drum	Incineration

7.4 Additional Waste Streams

It is the responsibility of the Departmental Managers to ensure that the Environmental Officer is contacted to confirm the correct disposal for any new waste streams that result from maintenance or project related operations on site.

8.0 DISPOSAL OFF-SITE

The documentation requirements for collection of waste and shipment off site is detailed in SOP 6.1025 Waste Management Policy.

STANDARD OPERATING PROCEDURE

SOP NUMBER: 6.1025	SOP VERSION: 2.0
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SIGNATURE INFORMATION

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Originated By:	Vicky Bow	Environmental Health & Safety	06/10/2003 12:34:21 pm
Reviewed By:	John Toner	Maintenance Engineering	14/1 112003 04:54:08 pm
Reviewed By:	Tony Carter	Environmental Health & Safety	14/11/2003 04:58:02 pm
Approved By Quality:	Ann Whelan	Quality Assurance	17/1 112003 09:59:15 am

Environmental Health & Safety
Maintenance
Entry T.H 12/12/03

FOR INFORMATION

Version	Revision Details	Effective Date
0	Original - Written to Comply with the Pfizer Corporate Waste Management Guideline 19, the PGM EHS Special Waste Management Procedure and Pfizer Quality Standard 13. This Sop also details the following: • The Documentation Requirements for Collection and Disposal of all Waste Streams Off-Site. • Control and Auditing of Waste Management Contractors. • Current Legislative Requirements. • Management of the Waste Area. • Updated Anninfo and EPA Reporting requirements.	25/09/2003
.0	Updated Section 11 .O to include details on waste collection and storage points as per Pfizer Quality Standard 13.	

1.0 PURPOSE

To Define the Waste Management Practices and Documentation Requirements associated with Waste Management On-Site and Waste Shipment Off-Site.

2.0 SCOPE

The EHS Department is the site waste disposal authority and is responsible for writing all waste related SOPs and ensuring that all waste management practices on site and all waste disposal off site is in compliance with applicable legislation, the site IPC Licence, the Pfizer Corporate Waste Management Guideline 19 and Pfizer Quality Standard 13.

3.0 ORGANISATIONAL UNITS AFFECTED

EHS Department
Maintenance / Engineering Department -Waste Handlers

4.0 RESPONSIBILITY

It is the responsibility of the Environmental Officer to ensure that the Waste Inventory is accurate and kept up to date.

It is the responsibility of the EHS Department to schedule the collection/shipment of all waste streams off site.

It is the responsibility of the waste handlers to maintain the waste area and trash room in an orderly manner and to label waste drums with the appropriate hazards and labels.

5.0 REFERENCES

- Pfizer Corporate Waste Management Guideline 19
- PGM EHS Special Waste Management Procedure
- Pfizer Quality Standard 13
- Waste Management Act 1996 and Associated Regulations
- Carriage of Dangerous Goods by Road Regulations, 2001
- European Communities (Safety Advisors for the Transport of Dangerous Goods by Road and Rail) Regulations, 2001.

- Disposal of Municipal Waste at Pfizer site is detailed in SOP 6.1004
- Disposal of Maintenance and Project Related Waste is detailed in SOP 6.1024
- Disposal of Laboratory Waste is detailed in SOP QCG009
- Disposal of Waste Bovine Material is detailed in SOP 6.1021
- Disposal of In Process and Finished Product Waste is detailed in SOP 6.1023

The SOP's detailed above describe waste streams and wastes generated in functional areas on site in further detail than this SOP. This SOP uses the broad categories of waste produced on site to further stipulate the specific disposal routes for each waste category.

6.0 PFIZER WASTE DESIGNATION

In line with the Pfizer Corporate EHS Waste Management Guideline 19, all waste streams on site are classified as either 'Special Waste' or 'Non-Special Waste'.
A definition for Pfizer Special and Non-Special Waste is detailed below:

Special Waste is any wastestream comprised of biological, radiocative 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 as non-special if the total wastestream volume **is** less than 100 kg 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.

7.0 CHARACTERISATION OF WASTE STREAMS

7.1 In line with the Pfizer Waste Management Guideline all waste streams for disposal on site have been characterised and defined as:

- Solid or Liquid
- Hazardous or Non – Hazardous
- Special or Non Special

7.2 These waste streams have been tabulated to form a waste inventory which details how the streams are managed, their EWC (European Waste Catalogue) Code, their storage arrangements and their final disposal route. The waste inventory is filed on the Central N Drive at the following location:
N:\S&H Management System\Pharm Facility\Environment\Waste\Waste Inventory\Waste Inventory 2003.xls

8.0 WASTE DISPOSAL ROUTES

For the purpose of this document waste disposal routes are divided into four main categories based on their disposal route/method of treatment and Pfizer Special or Non-Special Designation. These categories are as follows:

- Pharmaceutical Waste and Chemical Waste for Incineration
- Biological Waste
- Other Special Wastes
- Municipal Waste

The documentation requirements for transporting each Waste Stream off Site are described in detail below:

8.1 Pharmaceutical and Chemical Waste for Incineration

This includes the following wastes as detailed in the Waste Inventory: Pharmaceutical Waste, Chemical Waste, Packaging Waste Contaminated with Pharmaceutical Products, Filters Contaminated with Pharmaceutical Products and any other Hazardous Wastes.

It **is** the responsibility of the Environmental Officer to schedule and arrange waste shipments when instructed by the Waste Handlers. The Waste Handlers will make a list of all waste to be sent off site and the Environmental Officer will forward this to the Waste Disposal Contractors.

Additionally it is the responsibility of the Environmental Officer to commission an approved external company to come on site and pack 'lab smalls' and waste laboratory chemicals (as disposed into the waste cabinet in the Chemistry Laboratory) into UN approved drums suitable for shipping. Shipping of lab smalls off site takes place on an annual basis or more frequently depending on waste generation rates.

The following must be taken into consideration when preparing Pharmaceutical and Chemical Waste for shipment.

8.1.1 Packaging and Labelling

Liquids and Solids sent off site for disposal are, where appropriate classified, packaged and labelled in accordance with the relevant legal requirements.
This at a minimum includes:

- The use of UN approved drums/shipping containers
- Affixing the appropriate hazard identification label
- Removal of all other labels
- Securing the drums/containers on the shipping pallet where necessary

The Environmental Officer/ DGSA will advise the Waste Handlers on packaging and labelling requirements.

8.1.2 Analysis of Waste Streams

It is the responsibility of the Environmental Officer to ensure that a sample is taken from the following waste streams prior to shipment off-site:

- Chloroform Bovine waste
- Carbon Contaminated with Chloroform

This sample must be sent to an external consultant laboratory in order to determine the Chloroform Concentration of the Waste Stream in accordance with Condition 7.1.3 of the Site IPC Licence.

8. I.3 ***Security***

In line with the requirements of PQS 13 prior to leaving site, drums containing Pharmaceutical Vials are tagged with a unique identification number. These tag numbers are recorded and documented by the Environmental Officer prior to shipment. The Tag numbers are detailed on the Certificates of Destruction returned to Pfizer by the Waste Contractor Company.

8.1.4 Preparation of Load Plan:

A load plan is prepared for each 40ft container load, which leaves the site. The plan is prepared as the materials are being placed on the container. A copy of the load plan is held by the Environmental Officer and filed with all documentation related to the waste shipment.

8. I.5 Transportation of Waste:

It is the responsibility of the Environmental Officer/DGSA to ensure that the following documentation accompanies each waste shipment and that all documentation has been correctly completed.

- Cl Form – A Cl Consignment Note must always accompany hazardous waste that is being moved within Ireland. The Environmental Officer must complete Block 12 on Part A **of** the **Cl** form and witness the signature of the driver in Part B. The Environmental Officer retains the pink copy of the Cl Form.
- Cl Annex/ADR Document – The Cl Annex is attached to the Cl Form detailing any hazardous waste to be moved in the shipment. The Environmental Officer must ensure that Columns 2,3 and 5 in the Cl Annex/ADR Document contain the accurate information regarding the waste shipment, before signing and retaining a copy.
- Tremcards – If any material is hazardous for transport under ADR Regulations, the Environmental Officer/DGSA must ensure that the driver has signed the appropriate tremcards and take a copy of each.
- The Environmental Officer will complete an Audit Checklist of the Waste Contractor Vehicle prior to it leaving site. Copy of this audit checklist is located on the N Drive at the following location:

N:\S&H Management System\Pharm_Facility\Environment\Waste\Waste Shipment Audit **and** Checklist\Waste Shipment **Audit and** Checklist.doc

Copies of all documentation above are held by the Environmental Officer and filed in the EHS Department. All Details relating to the waste shipment are logged on a dedicated Excel Spreadsheet on the EHS Database.

8. I.6 *Records*

Once the waste has been accepted by the Waste Contractor Company at the transfer station, a Certificate of Receipt is forwarded to the EHS Department.

Certificates of Destruction detailing the TFS assigned to the waste and a copy of the yellow copy of the **Cl** Form with Part C Complete are forwarded to the EHS Department by the Waste Contractor following Incineration of the waste.

These records are filed with the transportation documentation for the load in the EHS Department. All records are held for a period of 7 years.

8.2 Biological Waste

Biological Waste Comprises of the following wastes as detailed in the Waste Inventory: Waste Bovine Material (which includes Reject/ Waste Bovine Lung / Serum and Plasma, Associated Bovine Packaging, and PLE Waste), Autoclaved Microbiology Laboratory Waste, Clinical waste from the OH Department and Sharps.

It is the responsibility of the Environmental Officer **to** schedule a Biological Waste Collection upon instruction of the Waste Handlers.

8.2. I Packaging and Labelling

All Biological waste is held in designated 400L Wbeelie Bins in the -20°C Waste Freezer. These bins are all labelled with the appropriate UN Number for the Waste.

Each 400L Wheelie bin is also labelled with a unique bin number and a client identification number for tracking during the processing of the waste.

8.2.2 Preparation of Waste for Transportation

The Waste Handlers will ensure that the inner liner in each bin has been securely closed with the cable tie and that the lids of each bin have also been sealed closed with an additional cable tie.

The Waste Handlers will furnish the Environmental Officer with details of the number of Wheelie Bins for collection and the specified bin numbers.

8.2.3 Transportation of Waste

It is the responsibility of the Environmental Officer/DGSA or nominated deputy to ensure that the following documentation accompanies Biological Waste shipments and that all associated documentation has been correctly completed.

The Environmental Officer must also ensure that the specified Wheelie Bin Numbers are detailed on the Transport Documentation

- Cl Form – The Environmental Officer must complete Block 12 on Part A of the Cl form and witness the signature of the driver in Part B. The Environmental Officer retains the pink copy of the Cl Form.
- Dangerous Goods Note – The Environmental Officer must complete the following information within the Dangerous Goods Note: Dangerous Goods Declaration, Cl Number, Total Number of Bins and Bin Numbers before witnessing the Waste Contractor signing to receive the waste. The Environmental Officer retains a copy of this form.
- The Environmental Officer will complete an Audit Checklist the Waste Contractor Vehicle prior to the container leaving site. As detailed in Section 8.1.5. This audit checklist is filed on the N Drive.

Copies of all documentation above are held by the Environmental Officer and filed in the EHS Department. All Details relating to the waste shipment are logged on a dedicated Excel Spreadsheet on the EHS Database.

82.4 ***Records***

Once the waste has been treated by Industrial Autoclave a Certificate of Destruction detailing the specific Wheelie Bin Numbers and a copy of the yellow copy of the Cl Form with Part C Complete are forwarded to the EHS Department by the Waste Contractor Company.

These records are filed with the transportation documentation for the load in the EHS Department. All records are held for a period of 7 years.

8.3 Other Special Wastes

As detailed in the Waste Inventory the following waste streams detailed in the table below are classified as Special Wastes and require specific transport documentation for movement off site.

Waste Stream	Waste Transport Documentation	Records
Oil	No Cl Form Necessary	Recovery Certificate
Batteries	Cl Form	Cl Form Recycling Certificate
Plastic/Steel Drums Contaminated with Chemical Substances	C1/Trem Cards	Cl Form Recycling Certificate or Certificate of Disposal
Interceptor / Drain Cleaning Waste	C 1 Form	Cl Form Certificate of Disposal
WEEE Waste	Cl Form	Cl Form Recovery Certificate
Fluorescent Lamps	Cl Form	Cl Form Recovery Certificate

8.3.1 Scheduling of Waste Collections

It is the responsiblility of the Environmental Officer to schedule Waste Collections for the Waste Streams detailed above upon instruction from the Waste Handlers/Maintenance Engineering Department or Project Engineering Department.

8.3.2 Waste Transport Documentation

All of these Waste Streams must be accompanied by a Cl Form with the exception of Oil Waste and must be transported in containers deemed suitable by the Environmental Officer/ DGSA.

8.3.3 *Records*

Upon disposal/ recycling **or** recovery of these waste streams the Waste Contractor Company forwards a Certificate of Disposal/Recovery to the EHS Department as detailed in the table above. These Certificates are filed in the EHS Department along with the associated transportation documentation.The Environmental Officer also logs this information on the dedicated Excel Spreadsheet on the EHS Database.

All records are held for the period of 7 years.

8.4 Municipal Wastes

This waste stream includes the following non-special waste streams as detailed in the Waste Inventory: Municipal Waste, Canteen Waste, Paper Waste for Recycling, Newspapers and Magazines for Recycling, Metal Waste, Printer and Toner Cartridges, Glass Waste / and Aluminium Cans.

It is the responsibility of the Waste Handlers to schedule the disposal of the Municipal Waste and Canteen Waste Streams.

It is the responsibility of the Environmental Officer to schedule disposal of the remaining waste streams detailed above waste streams where necessary.

All Documentation relating to these waste streams including Skip Documentation, Collection Certificates, Certificates of Disposal and Certificates of Recycling are held in the EHS Department and logged on the dedicated Excel Spreadsheet on the EHS Database.

All records are held for the period of 7 years.

No records are held for the Recycling of Glass Bottles and Aluminium Cans.

9.0 REQUIREMENTS RELATING TO THE TRANSPORTATION OF WASTES

9.1 Colleague Training

Pfizer Colleagues who handle and transport waste on site must be trained with respect to the following:

- Safe practices for carrying out their assigned responsibilities
- Legal requirements for handling and transporting waste
- Hazards of Waste

9.2 Requirements for the Transporters of Special Waste

Vehicles employed by Pfizer for the transportation of waste must be properly authorised for that purpose as required by law. This requirement is addressed through the holding of waste collection permits for all waste contractors used.

Details of the Waste Contractor Permits and Associated licences are filed on the Central N Drive at the following location:
N:\S&H Management System\Pharm Facility\Environment\Waste\Waste Contractor Collection Permits and Licences\Contractor Waste Collection Permits and Licences.xls

9.3 Hazard Warning Provided to Waste Management Contractor

Pfizer Dublin must disclose to the waste management contractors, in writing, the hazards, known to Pfizer associated with the handling of the special waste.

These warnings must:

- Accurately characterise the waste
- Be accurate to protect the employees of transporters and contractor waste handlers
- Warn of any potential environmental impacts, either from unplanned releases or through planned waste management

9.4 Dangerous Goods safety Advisisor (DGSA)

It is the responsibility of the site DGSA to ensure that all Waste Shipments sent off site are in compliance with the rules governing the transport of dangerous goods.

9.5 Cl Consignment Notes

It is the responsibility of the Environmental Officer to ensure that an adequate number of Cl consignment notes are held on site for waste shipments.
Cl Consignment notes are obtained from Dun Laoghaire-Rathdown County council at a price of • 20 each. Payment must be accompanied with a letter of request to the Executive Waste Management Engineer.

10.0 SELECTION OF WASTE CONTRACTORS

Waste Management Contractors who manage Pfizer generated Special Wastes in excess of 100 Kg per year are subject to criteria for selection and audit prior to use and on an ongoing basis at intervals of 4 years.

10.1 Pfizer Ireland Waste Management Team

The Pfizer Ireland Waste Management Team is comprised of a member of the EHS Department from all Pfizer Sites in Ireland, who is responsible for waste Activities.
The team meets on a monthly basis at the Pfizer Loughbeg Drug Substance Plant in Cork. To discuss items pertaining to Waste Management Contractor Selection and Waste Management Contractor Auditing. The team schedules and oversees the auditing of all Waste Management Contractors who manage Special Wastes in line with the Pfizer Corporate Waste Management Guideline 19 and PGM EHS Special Waste Management Procedure.

10.2 All Waste Management Contractors who manage Pfizer generated Special Waste are audited for compliance and the following documentation is submited to corporate for approval

- The Pfizer Pre-Audit Questionnaire. This questionnaire was developed by Pfizer Loughbeg. A copy of this questionnaire is located on the N drive at the following location:

N:\S&H Management System\Pharm Facility\Environment\Waste\Pfizer Waste Management Team\Waste Contractor Pre Audit Questionnaire.doc

- The Special Waste Vendor Report. A copy of this report template is located on the PGM Website as follows: http://pgm.pfizer.com.

All original copies of Waste Contractor Audits for Ireland are held in Pfizer Loughbeg.

10.3 Only Special Waste Management Contractors on the 'Group Approved List' are used by Pfizer Dublin. The Group Approved List of approved Waste Management Contractors is located on the PGM Website at the following location: http://pgm.pfizer.com.

New facilities that are not on the group approved list may only be used to manage Pfizer Generated Special Waste following a pre-selection audit and approval from group.

10.4 Additionally each Pfizer Ireland facility maintains a list of Waste Management Contractors used by that site detailing the last audit date and next proposed audit date for each Waste Management Contractor.
A list of the Waste Management Contractor Audit details for Pfizer Dublin is filed on the N Drive at the following location:
N:\S&H Management System\Pharm Facility\Environment\Waste\Waste Contractor Audit Information\Waste Contractor Audit Information.xls

11.0 MANAGEMENT OF THE WASTE AREA

It is the responsibility of the waste handlers to maintain the trash room, waste area and associated waste cabinets in a clean and tidy manner. It is also the responsibility of the waste handlers to ensure that the gate to the waste area and doors of the waste cabinets are kept closed and secured at all times.

It is the responsibility of the waste handlers to collect all waste streams from the various storage points throughout the plant on a timely basis in order to prevent the accumulation of waste material. In accordance with PQS 13 all waste collection and storage points must be separate from Production **Modules.**

These waste streams should be stored in the trash room and the waste storage area prior to disposal off site.

12.0 REPORTING REQUIREMENTS

12.1 Reporting to the EPA

The following waste Related Reports must be submitted to the EPA.

12.1. I Bi-Annual Monitoring of Waste of Site

This report is submitted to the Agency bi-annually on 10th July and 10th January every year detailing **the following** information for the previous six month period:

- Waste Stream
- Quantity of each Waste Stream
- EWC Code
- Destination of each Waste Stream

The report also details the chloroform concentration of the Chloroform Bovine Waste and Carbon Contaminated with Chloroform Waste Streams.

12.1.2 Annual Waste Summary Report

This report is submitted to the Agency with the Annual Environmental Report and includes the following information:

- Waste Stream
- EWC Code
- Transporting Agent
- Disposal Site
- Disposal Method
- Quantity of each Waste Stream

12.2 Anninfo Reporting

The following must be submitted to Anninfo on an Annual basis

- Mass of Special and Non-Special Waste Resulting from Routine and Non-Routine Operations
- Waste Streams that are not yet managed by an acceptable method (In accordance with Attachment 19A of the **Pfizer** CorporateWaste Management Guideline 19)
- Each Waste Stream greater than 1,OOOKg per month that is managed by a conditional method, unless an assessment of the method has be completed and found to be acceptable by Group EHS and Corporate EHS.