Emergency Response and Accident Prevention Procedures

PURPOSE

This provides a description of the plans for the Management of Emergencies in accordance with the Emergency Plan (Ref 1.). Separate procedures describe how emergencies are responded to (Ref. 2, Ref. 3, Ref. 4). The purpose of the procedure is to ensure that for all potential major emergency scenario's identified there is a structure and plan in place to manage major emergencies, provide information and assist the emergency services. The activities taken to prevent and control Major Accidents are contained in the Major Accident Prevention Policy (C-EHS-POL-002, attached)

SCOPE

This procedure identifies the roles and responsibilities of key personnel, and the arrangements for contact & communications, both in planning for and in managing Major Emergencies. It details the process for conducting audits and review of Major Emergency Management arrangements. Incidents arising from terrorist or security breaches are not covered by this procedure. The Emergency Management organisational structure is detailed in Figure 1.

A Major emergency is defined as:

- Large Uncontained Fire
- Explosion •
- .
- •
- Significant Toxic Release Serious Injury or Fatality Significant Off-Site impact Any scenario likely to result in significant production downtime or product loss or which could adversely affect the company's reputation in any way.

A major emergency may be precipitated by an outside force, such as a severe electrical storm, crashed aircraft, deliberate acts of arson, sabotage, civil strife or a serious off-site emergency which threatens to impact on the site copyrigh Form either physically or operationally.

The Major Emergency Management Team (MEMT) will provide any responses needed to:

- Government Departments and Regulatory Agencies requirements.
- BMS personnel •
- The general public
- The Media

RESPONSIBILITIES – PLANNING FOR MAJOR EMERGENCIES

General Manager 1.1

- When available, acts as Duty Emergency Commander (DEC) to the MEMT in a Major Emergency. .
- Has overall responsibility for ensuring that adequate resources and structures are in place to deal • adequately with major emergencies, including out-of-hours arrangements (Ref. 5)
- Ensures the MEMT is adequately trained and drilled to handle any major emergency scenarios • identified.
- Ensures that the site Major Emergency Management arrangements are periodically tested and reviewed, in accordance with predetermined criteria in Table 1.

1.2 **EHS Director**

- Ensure that maps of the local area are available at the Emergency Control Centre to facilitate the Gardai or others in notifying local residents of any major problems which could arise.
- Ensures any fire, safety or rescue equipment and information are provided and maintained in the .

Emergency Operations Room (Wexford Room).

- To ensure that the Emergency Operations Plan and general documentation is up-dated as necessary to take account of changing circumstances
- Ensure all relevant drawings, procedures, information regarding storage and quantities of • chemicals, etc. are available at the emergency control centre (Wexford room) and updated as necessary, and that key personnel are kept informed of what is expected of them.
- To ensure that all necessary equipment to deal with a spillage is available for emergency purposes. .
- Consults, on an on-going basis with the local emergency services on site specific hazards, . emergency response equipment and local emergency response and management issues.
- To head-up the follow-up investigation team. .
- To compile and circulate notifications & report of incident to HSA, EPA, BMS CAS, BMS Worldwide • Medicines Group EHS, Fingal County Council, where necessary, in a timely manner.
- Provides advice and direction in relation to major emergency management policy. •
- Maintains an up-to-date list of key contacts in an emergency.
- Ensures all major emergency scenarios are identified and assessed as described in the Major . Accident Prevention Policy (Ref. 6).
- Ensures that adequate emergency management arrangements are provided for all scenarios identified for Major Accident Scenario Modelling (Ref 8.).
- Ensures that safe shutdown procedures (manual or automatic) are identified for all area operations . in the event of a major emergency.
- Forms part of MEMT. •
- Maintains the DEC rota. •
- Facilitates and organises drills for the MEMT.

1.3 Duty Emergency Commander (DEC)

- PS-S ON TOT ANY OTHER USE Acts as Senior site Manager during a Major Emergency, until replaced by the General Manager .
- Carry the Major Emergency bleeper and bag, and is available on call-out. .
- Mobilises and Leads the MEMT Major Emergency .
- Assigns any duties required by the MEMT. •
- Is selected from the following group: •
 - General Manager
 - Manufacturing Director
 - Security Director
 - Finance Director
 - EHS Director
 - Technical Services Director
 - MT Director

Technical Services Director 1.4

- Acts as DEC on a rota basis. .
- Ensure that any updates of Site Maps, Drawings etc. are provided to EHS to enable effective • isolation of plant, storage tanks, gas mains, etc.

1.5 **Manufacturing Director**

- Acts as DEC on a rota basis.
- Participates in MEMT

1.6 Security Director

- Where available, directs security activities during an emergency
- Participates in MEMT
- Ensure that the security staff are trained and drilled in their duties in an emergency situation, and •

are capable of dealing with any problems which may arise.

1.7 Finance Director

- Ensures that finances are available to manage Major Emergencies
- Ensures alternative means of personnel & contractor payment are deal with all contingencies.
- Participates in MEMT

1.8 Major Emergency Management Team (MEMT)

- Participate in MEMT where mobilised and available.
- Respond to mobilisations and perform whatever duties assigned by the DEC.
- At least 8 MEMT members should be mobilised. The team is drawn from the following group:
 - General Manager
 - EHS Director
 - Manufacturing Director/Managers
 - HR Director/Manager
 - TOG Manager
 - Technical Services Director/Manager
 - Utilities & Maintenance Managers
 - Materials director/Manager
 - Facilities Manager
 - IT Director & AIM Manager
 - Q.C./Q.A. Director/Managers
 - Safety/Environmental Manager 410

RESPONSIBILITIES – DURING A MAJOR EMERGENCY

Con

1.9 Duty Emergency Commander (DEC)

1.10 General Responsibilities:

The Duty Emergency Commander assumes overall responsibility for all matters during a major emergency. This will be either the General Manager (where on-site) or in their absence a designated Senior Manager. Based on the availability, the DEC will appoint person(s) to carry out the duties functions in Sections 7-9.

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The Duty Emergency Commander (DEC) will direct, control and monitor all operations in the event of a serious emergency, so as to minimise injury, or death to people, or damage to property or the environment. They will ensure efficient liaison between Company personnel and external agencies and accurate dissemination of information. S/He will direct operations from the Emergency Control Centre (Security Building) or other area which he deems to be appropriate, depending on prevailing circumstances.

- Ensure key personnel and services are mobilised and notified as required.
- Mobilise the MEMT.
- Ensure that all evidence is preserved to facilitate any subsequent investigations, and that a contemporaneous record/log of events is maintained throughout, and photographs, video recordings taken as necessary.
- Maintain communications with outside Fire Brigade Officers and Gardai and provide any assistance which they may require including provision of details of the Fire Protection system.
- Handle media and public enquiries, and/or notify relatives if appropriate.

1.11 Specific Responsibilities:

Immediately upon notification of a serious emergency the DEC will go to the Emergency Control Centre (Wexford Room) and will consider the following:

- Assume overall control of the situation, and ensure that this procedure is put into effect.
- Secure access & egress to the site
- Activate alternative communication systems .
- Ensure contact the neighbours and Management of adjacent Companies and inform them . of the situation.
- Notify or instruct the any outside agencies, such as Gardai, Health and Safety Authority, Environmental Protection Agency, Fingal County Council.
- Initiate contact with the following BMS Groups: Worldwide Medicines EHS, European Vice President Technical Operations, Technical Operations Legal Counsel, Corporate Compliance Assurance Services.
- Ensure that adequate information is available & provided to the Chief Officers of the Fire Brigade and the Gardai, and that they are made aware of any effects which the emergency could have on areas or personnel outside the site.

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- Ensure that the impact on the site production schedule is assessed and determine if suppliers I customers or insurers need to be notified.
- When the emergency has passed, decide when re-occupation may take place..

1.12 Human Resources Controller

1.13 General Responsibilities:

In the event of a serious emergency the HR Director/Manager opin their absence, a designated member of the MEMT, will ensure that all possible efforts are made to alleviate hardship to the Company's employees and any other personnel on site. They will also ensure that only correct information is released to the media, if possible at a tinsection price time when it will not have a distressing effect on relatives or friends of those involved. This would normally be the HR, Security or EHS Director.

1.14 Specific Responsibilities:

- For Maintain a comprehensive listing of injured personnel on the site by liaising with the Eastern Health Board.
- If there are chemical injuries, ensure that any relevant Material Safety Data Sheets are transmitted with the injured for the attention of the hospital medical staff.
- Ensure that next of kin of dead or seriously injured are notified of the situation as soon as possible. In this regard, assistance from the Gardai is likely to be necessary.
- Ensure that a hard copy list of all employees' names, home addresses and next of kin is available in an emergency.
- Identify and attempt to alleviate any serious hardship caused to next of kin, where possible.
- Prepare draft information releases for the news media in conjunction with the Company Public Relations Company, for use in an emergencies, to cover all emergency scenarios identified (C-EHS-POL-004).
- Where the emergency is prolonged, arrange for relief of personnel, where possible, and provision of food and drink as necessary.

1.15 Technical/Process Controller

1.16 General Responsibilities:

A designated member of the MEMT advises on technical, Process or site utilities and facilities. This would normally be the Manufacturing, Technical Services or MT Director

1.17 Specific Responsibilities:

- Be available at the Emergency Control Centre (Wexford Room) to advise the DEC on relevant matters.
- Provide advice/assistance on stored chemicals and site utilities.
- In consultation where necessary with the DEC, Manufacturing, Technical Services and the Incident Controller, ensure safe shutdown of plants, utilities and other necessary precautionary measures.
- Ensure that Maintenance goes to the fire pumphouse, and verify the normal operation of the fire protection system, pumps and the fire water system.
- Ensure that any updates to Site Maps, Drawings etc. are provided to EHS to enable effective isolation of plant, storage tanks, gas mains, etc.
- Ensure that operations at the pumphouse are maintained in that area to enable those in attendance to act in the most effective manner.
- When the emergency is brought under control, assess the possibility of further problems (e.g. Utilities) which might affect personnel on being allowed to return to work.
- Provide advice/assistance on stored chemicals and site utilities.

1.18 Environmental Health and Safety Controller

1.19 General Responsibilities:

A designated member of the MEMT who advises on regulatory matter and liaises with the ERT and the Emergency services. This would normally be the EHS or Security Director.

- Provides advice and assistance in relation to regulatory notifications and compliance
- Maintain communications with the Incident Controller/ERT so that full and correct information is available at all times available.
- Advises the DEC on regulatory aspects/requirements of the emergency.
- Acts as point of communication with the emergency services
- Monitors emissions and provides safety/environmental data where required
- Verify any spillages and fire water are fully contained and routed to appropriate contained areas.
- Provides assistance to the fire and rescue services on site layout, stored chemicals, location of utilities

1.20 Specific Responsibilities:

- Where appropriate, visit the scene of the emergency in order to assess the seriousness
 of the situation at first hand, and thus be better equipped to advise the DEC regarding
 action required.
- Set up the Emergency Control Centre (Conference Room).
- Organise for any on or off site environmental monitoring to be carried out if required.
- Carry a radio.
- Notify Health and Safety Authority, Environmental Protection Agency, Fingal County Council, etc.
- Notify BMS Worldwide Medicines Group EHS and Compliance Assurance Services (CAS).
- To advise the DEC on various aspects of Health, Safety and Environment, as may be appropriate, depending on the nature of the emergency.
- To ensure that resetting of any alarms is carried out as soon as it is practicable.
- To head-up the follow-up investigation team.
- Seek and provide advice on likely health effects, chemical reactions, and specific spill control requirements.

1.21 Security Controller

1.22 General Responsibilities:

A designated member of the MEMT advises on security matters during a major emergency who will be to control access and ingress to the site; direct enquiries or communications to the MEMT; participate in evacuations. This would normally be the Security, Technical Services or EHS Director.

1.23 Specific Responsibilities:

- Assume responsibility for the control of traffic onto and off the site.
- Provide any keys required. .
- Preserve the scene for investigation .
- Record in real-time all details of the emergency, names of emergency services personnel involved, the chronology of events etc., and organise for any photo's to be taken.
- When the emergency is brought under control, assess the possibility of further problems (e.g. Utilities) which might affect personnel on being allowed to return to work.

other use.

- Sets up and operates the emergency telephone system
- Manage site communications issues.

PROCEDURE

1.24 General

Where an incident develops into a Major emergency, this section of the Emergency Plan is brought into action. tion purposes

1.25 Duty Emergency Commander (DEC)

Duty Emergency Commander (DEC) From 5.00 pm on a Monday, until the following Monday morning designated Senior managers will on a rota RALE FOT basis, act as DEC.

1.26 Mobilisation of Major Emergency Management Team (MEMT)

Where an emergency occurs, the Security Centre will be manned by the Incident Controller (IC), and the Security Officer(s) on duty (Ref 9). If the IC considers the incident serious enough, the IC will notify the DEC who will decide whether or not to mobilise the MEMT.

1.27 Major Emergency Management Team

1.28 Declaring a Serious Emergency

The authority to declare a major emergency rests with the DEC, normally the General Manager or a senior Manager who assumes the role of DEC.

The Security Building will be used as the Incident Response centre. Major Emergencies are controlled from the Administration room, or if not possible on site, in Swords. All the information and equipment needed to manage a Major Emergency will be located in a mobile cabinet located in the Wexford Room.

1.29 Mobilising MEMT and Key Services

Where a major emergency is declared during Office hours (normal working), designated MEMT Managers will report directly to the Emergency Control Centre (Conference room) or off-site as appropriate. Depending on who is available, the DEC will designate the various controllers identified in section 4 of this procedure.

On shift, the Fire Brigade and other emergency services will be notified by the Incident Controller or the DEC.

On shift at the direction of the DEC, MEMT members are to be contacted by telephone by the Incident Controller and/or Security. Announcements may be made via the PAVA system. The DEC will decide whether to notify the Fire Brigade, Ambulance Service and Gardai if not already on site.

A list of emergency contacts for Key Personnel and Services is maintained (Ref 10.).

Once the MEMT has assembled, from the Managers available the DEC will nominate MEMT members to act as Technical Services, EHS, Security and HR controllers and others as appropriate, to perform the duties identified in Section 4.

1.30 Rescuing and Treating Casualties

All rescue efforts will be made by members of the ERT and the first aid teams until the external emergency services such as Fire Brigade and ambulance personnel arrive (Ref.11). Upon direction from the Incident Controller, ERT members will search affected areas to make fire damage assessments, identify any other hazards and search for casualties.

All casualties are to be removed to an appropriate safe area (normally canteen) for first aid and then by the emergency services for further medical treatment or examination, or removal to hospital, as required.

Priority for transportation to hospital will be determined by degree of injury, at the discretion of the emergency services in charge. Appropriate information should be provided to accompany any casualties going to hospital.

1.31 Contact with Emergency Services

The EHS controller to liaises with the Emergency Services/Fire Officer.

If a fire, explosion or spill involving chemicals occurs, and hazardous gases or large emissions of hazardous/flammable gases occur, local residents and schools/businesses which may be affected are to be notified. The MEMT will request the Emergency Services to inform those thought likely to be affected, as a matter of urgency. If there is danger of explosion, the same measures may need to be taken. In the case of emission of hazardous gases, local people may have to be evacuated to a safer area. However in most cases it is more suitable to ensure closing of windows and doors and warning people to stay indoors for a period of time.

Portable environmental monitoring equipment will be maintained capable of detecting airborne concentrations of gases and or acid/solvent vapours

The DEC will decide if neighbouring businesses and companies need to be advised of the situation, and asked to take appropriate measures to safeguard their personnel. Key Emergency Contact details are maintained (Ref.10).

All non-essential personnel should be evacuated off site, and persons arriving at the site may need to be redirected. If there is the possibility of a deterioration of the situation or prolonged unsafe conditions, the DEC may decide to evacuate to a more suitable area off site base.

1.32 Minimising Damage to Property and the Environment

All possible efforts should be made to contain the emergency within the site, and to prevent environmental pollution.

Major spillages of chemicals should be dealt with in accordance with the Company procedures (Ref. 9) or in consultation with the EHS or Chemical Controllers.

Spillages of hazardous materials should be routed to containment areas, and every effort should be made to ensure that no spillage is allowed to drain to surface water.

1.33 Regulatory Notifications

In the event of a serious emission the Environmental Protection Agency and Fingal County Council are to be immediately informed by the EHS Controller.

The Health and Safety Authority will be informed of any notifiable incidents, in accordance with Site procedures (Ref. 7).

1.34 Containing and Controlling the Emergency

Every opportunity should be availed of to contain the emergency within a specific area. Where a clear assessment of the overall position is possible, after the search team has reported back, the DEC will make every effort to minimise damage and contain the emergency.

The DEC may have to order a fall-back position in order to prevent danger to the lives or health of ERT or first aiders.

1.35 Notifying Relatives

The HR Controller will liaise with the Emergency Services to compile lists of injured, and to contact next of kin.

1.36 Allowing Personnel back to Affected Areas

In a serious emergency, the DEC will determine when/if a safe reoccupation of affected areas is possible, based on personal examination and after due consultation with the MEMT and any appropriate emergencies and third parties.

1.37 Preserving the Evidence

To facilitate investigation of the incident, the scene of the emergency may need to be preserved as far as possible by the Security Controller.

Items of plant and other equipment in the area are to be left undisturbed, except by rescue personnel or to extinguish a fire.

The effected area should be cordoned off and entry restricted.

All records relevant to the affected area, such as Maintenance records, EHS, Production, and Safety Inspections, etc., are to be gathered and maintained with the Emergency Control Centre records of the emergency.

1.38 Releasing Information

150 To ensure that authoritative and correct information only is released to the news media, the HR Controller shall be the only person authorised to release such information.

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EMERGENCY CONTROL CENTRE



The following materials, equipment & information will be maintained by EHS at the Emergency Control Centre (Wexford room):

- Drawings of the showing the location of buildings buildings, storage tanks, drum storage areas^o fire hydrants/fire pumps/fire water system, spillage containment areas, drainage arrangement, air emission vents, etc.
- Fire fighting equipment and materials
- Detail of assembly points and casualty treatment areas •
- Lists of employees by area for wardens
- A map of the surrounding area showing access points to the facility and the locations of houses, schools, other companies, environmental features etc.
- Drawings of individual buildings showing access points to utilities (gas, electricity, water, stored chemicals)
- A list of all employees addresses and telephone numbers and next of Kin.
- Note pads and pens. •
- Evacuation checklists for all Company personnel. •
- Copies of all Emergency Plans and Procedures. .
- Hard copies of Material Safety Data Sheets.
- Details of bulk tank contents and drum store inventories.
- Manufacturing and Tech. Services process flow sheets.
- Key Personnel List/Contact Numbers & Key Emergency Telephone Numbers.
- ERT/First Aiders Registers.
- Details of fire water retention pond and drainage systems
- Copies of Emergency Response Procedures .

- Site plans that can be marked up to show the development of an incident and the deployment of emergency response resources, areas evacuated and other related information.
- Log book to maintain a record of all messages sent and received
- Fully charged Mobile Phone
- Camera and Camcorder

1.40 Alternative Emergency Control Centre:

In case the Conference Room is damaged or unusable, the Waterford Room will be used as an alternative Emergency Control Centre. Should both of these be unsuitable, the Main DEC will decide what alternative course to follow – e.g. relocation to Swords laboratories.

AUDIT & REVIEW

The testing, monitoring and auditing of this Procedure and arrangements is the responsibility of the General Manager. The Procedures will be tested and reviewed at least annually against the criteria listed in **Table1**.

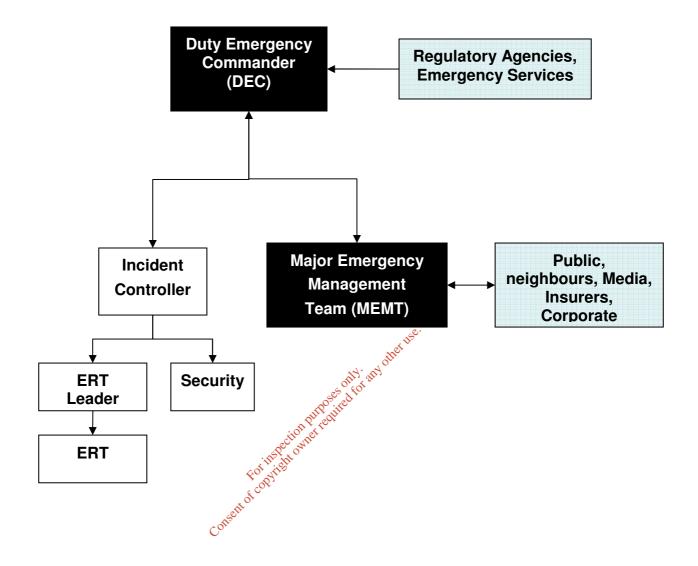
Table 1. CRITERIA TO BE INCLUDED IN MAJOR EMERGENCY RESPONSE TESTS AND REVIEWS

Type of Test	Content	Criteria for success	Carried out by:
1. Simple data verification.	1. Administrative check of the information contained in emergency plans, and documentation held in the Emergency Management Centre. 2. Make amendments to the information as its necessary.	1. The information is accurate and up to date.	General Manager or designated MEMT personnel.
2. Detailed incident scenario.	 Planned scenario exercise with predetermined objectives. (The scale of the exercise to be determined - may sometimes involve external stakeholders). The exercise is reviewed by participating personnel, observers and MEMT and lessons learnt identified & communicated. 	 Demonstration that staff are available to respond promptly and the site communications network works. Evidence that staff make decisions in accordance with the Emergency response and management Plans, policies & procedures. The objectives set are achieved and performance standards met. Any lessons learned are built into the system to improve future performance. 	 Exercise planned and conducted by General Manager, EHS Director & Security Director. Review of performance by MEMT & participants.
3. Real Incidents.	1. A review of the response to the incident by the participants led by EHS function.	 The incident results in a response that puts into practice the major emergency arrangements. Demonstration that staff are available to respond promptly and the communications network 	1. EHS Director.

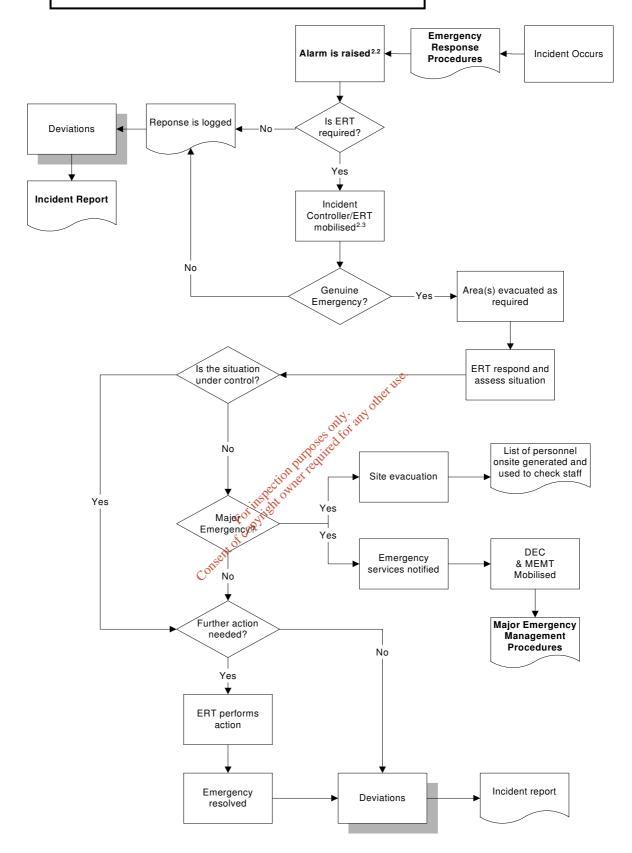
Type of Test	Content	Criteria for success	Carried out by:
		is operational.	
		3. Evidence that staff make decisions in accordance with the Major Emergency Procedures and plans.	
		4. Any lessons learned are built into the system to improve future performance.	

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FIGURE 1. MEMT ORGANIZATION CHART



PROCESS MAP – EMERGENCY PLANS



REFERENCES

- 1. C-EHS-POL-005, Emergency Plan
- 2. C-EHS-SOP-020, ERT Management
- 3. C-EHS-SOP-036, Emergency Response Procedures, ERT
- 4. C-EHS-SOP-089, Emergency Response Procedures, Incident Controller
- 5. C-EHS-FORM-048, Public Enquiry & Complaint Form.
- 6. C-EHS-POL-004, Major Accident Prevention Policy
- 7. C-EHS-SOP-009, Government Agency Inspections, Incident Notifications
- 8. Major Accident Scenario Modelling and Risk Assessment, PM Doc Ref 010568-23-RP-002
- 9. C-EHS-SOP-045, Spill Control procedure
- 10. C-EHS-RGT-007, Key Contacts in an emergency.
- 11. C-HR-SOP-007, Care of Injured Employees

ABBREVIATIONS / GLOSSARY

Phrase	Explanation
EHS	Environmental Health and Safety Department
SOP	Standard Operating Procedure
DEC	Duty Emergency Commander
MEMT	Major Emergency Management Team
ERT	Emergency Response Team

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Department / Title	Print Name	Signature		Date	
Prepared By: Safety Manager	O. Cronin	O. Cronin		02-AUG-2005	
Approved By HR Manager	L. Prendergast	L. Prendergast	L. Prendergast 15-		
Approved By: Tech Services Director	P O Sullivan	P O Sullivan		04-AUG-2005	
Approved By: Manufacturing Director	S. Kelly	S. Kelly		30-AUG-2005	
Approved By: EHS Director	I. Boyle	I. Boyle		16-AUG-2005	
Approved By: General Manager	V Surapaneni	V Surapaneni		13-SEP-2005	
Evonne Meaney	19-OCT-2005	012000, 10.00	Copy No.:	PDF	

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Document Title	~	MAJOR ACCIDENT PREVENTION POLICY					

1 Purpose

To describe the management systems in place for control of major accident hazards and prevention of major accidents in accordance with the European Communities (Control of Major Accident Hazards Involving Dangerous Substances) Regulations, 2000 (Ref 1) and in keeping with the site's overall safety management system as described by the Safety Statement (Ref 2)

2 Scope

In accordance with the Seveso II regulations implemented in Ireland by EC (Control of Major Accident Hazards Involving Dangerous Substances) Regulations, 2000 (Ref 1) the scope of this document is to outline the management systems in place at Bristol-Myers Squibb, Cruiserath, for "the prevention of serious industrial accidents or limitation of damage in the event of an accident and the avoidance of environmental damage".

In particular, Regulation 10 of SI 476 stipulates that it shall be the duty of every operator to prepare a document which specifies the manner in which major accidents are to be prevented (to be referred to as the Major Accident Prevention Policy or MAPP).

The expected inventories for bulk storage potential of hazardous chemicals throughout the site a d urposesed have been analysed and the site qualifies as a jower tier' Seveso site (Ref 12).

3 **Policy Statement**

The following is a statement of general major accident prevention policy for the BMS Cruiserath site.

"It is the policy of the Company to provide the maximum degree of safety, health and welfare for its employees and visitors while on Company premises and to ensure the elimination, containment and/or minimisation of all foreseeable major hazards posed by the activities of the plant to employees, visitors, neighbours and the environment. The Company will respond to any request for information, and will make such information available (providing it is not of a commercially sensitive nature) to the Health & Safety Authority, the competent authority for implementation of the EC (Control of Major Accident Hazards Involving Dangerous Substances) Regulations, as is required in order for them to adequately assess the risk of major accident and full-fill their obligations under the regulations in respect of land use planning.

The company shall provide for the design and maintenance of plant and machinery, instruction, training and supervision and such information as is necessary to ensure the safety health and welfare of all personnel. The Company will comply with all legislation and associated codes of practice relating to the safety, health and welfare of personnel under its control. Management at all levels, is responsible for safety. The company will ensure that qualified personnel, with clearly defined responsibilities and authority, are assigned to make sure that all activities on its premises afford appropriate protection against major accident hazards. Every Manager or Supervisor who directs or controls the work of others is responsible for the safety of these workers. The Manager/Supervisor will ensure that adequate safety facilities are available and safety procedures and codes of practice are adhered to at all times and is also responsible for the safety of equipment and property within their area of responsibility.

Every employee has a responsibility for their own safety and that of fellow employees. In the performance of their duties they shall observe all Company rules and procedures relating to the safe performance of their work which might endanger health and safety. It must be the intention of all employees to make the work place as safe as possible. Safety is an important aspect of

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assessment of any employee's work since working safely is a condition of employment.

The company has in place risk assessment, preventative maintenance and auditing programmes as a check of performance of high integrity safety controls and protective systems. These assessments and audits will cover the buildings/areas occupied by employees but also the equipment used and the method of work employed. Risk assessments and audits will be carried out by members of staff who are trained and competent in this process, but the participation, cooperation and contribution of all those with the appropriate skill and knowledge is an essential requirement of the process.

BMS-Cruiserath fully endorses the BMS World Wide Medicines Group Process Safety programme. This programme establishes guidelines to prevent or minimise the consequences of major accidents involving chemicals through appropriate hazards testing and process safety review procedures. Incorporating this programme into the pharmaceutical development pipeline will ensure that facilities are designed, constructed and operated to a high degree of safety.

BMS-Cruiserath participates in the Irish Pharmaceutical and Chemical Manufacturers Federation Responsible Care programme, which calls for the management of site activities in order to ensure an acceptably high level of protection for the heafth and safety of employees, customers, the public and the environment. In keeping with these guiding principles, the Company operates in a manner that preserves the environment and protects the safety of employees and the public, operates in accordance with relevant statutory obligations, recognises and responds to community concerns about chemicals and operations and makes available information concerning activities that affect health, safety and the environment to employees, the public and statutory bodies."

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Organisation and Personnel 4

An organisational chart is available (Ref 5) which outlines the general organisational structure for the whole site. An organisational chart outlined the specific organisational structure in place for major accident prevention is given in Appendix 1

Any changes to the organisational structure which impact on the MAPP contents are controlled through the site's change control procedures (Ref 3).

4.1 Selection and Recruitment

To hire a new employee, a Job Profile is prepared by the Department Manger which sets out the minimum education and training level, the experience requirements and core competencies for the position. Compliance with all aspects of the EHS management programme (including the Major Accident Prevention Policy) is a core requirement on every job profile. This analysis is followed up by interviews carried out by the recruiting manager and HR, using a guideline interview assessment form, which rates the interviewee. An Employee Appraisal-Probation Report form is completed before the end of the probation employment period and periodic performance appraisals take place thereafter based on Performance Partnership. One of the outcomes of performance is a training needs analysis which then feeds the training plan for that employee. More detail on these policies and practices are given in the Recruitment and Selection Policy (Ref 33) and in the Performance, Partnership programme (Ref 34)

4.2 Roles & Responsibilities

The roles and responsibilities, with regard to the safety management system, of all personnel and contractors are outlined in the Safety Statement (Ref 2). However, certain personnel have particular responsibilities in the prevention of major accidents and these are outlined here: ofcor

4.2.1 General Manager

Assume the role of Main controller in a major emergency in accordance with the documented Emergency Management Strategy for the site (Ref 16)

4.2.2 EHS Director

- Ensure Implementation of the requirements of the Seveso II Regulations
- Ensure adequate EHS departmental resources are allocated to the overall management of major accident prevention.
- Provide key input in establishing and tracking progress relating to objectives set as a result of the identification and evaluation of major accident hazards.
- Ensuring regular audit of the systems outlined in this document as part of the site's annual EHS audit programme.
- Member of the Strategic Response Team in a major emergency.

4.2.3 Safety and Loss Prevention Manager

- Responsible for co-ordinating the identification of major accident hazards and major emergency scenarios in all areas.
- Assist in the identification of suitable controls in all areas for the prevention of major accidents and the mitigation of their consequences.
- Ensuring that appropriate response procedures are documented and training provided in order to provide an adequate response to all identified major accident scenarios.

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 Manage the on-site Emergency Response Teams Liase with local emergency services with respect to familiarisation with site hazards, emergency response equipment and carrying out of drills. 							

- 4.2.4 Process Safety Engineer
 - Collate all hazard information from process development stages for new or modified processes introduced on site and where necessary to organise hazard testing in accordance with the site Process Hazard Analysis Procedure (Ref 17)
 - Co-ordinate Hazard and Operability (HAZOP) studies on new and modified processes and new and modified equipment in accordance with the site HAZOP procedure (Ref 18)
- 4.2.5 Maintenance Manager
 - . Maintain all records of maintenance and inspection of all process equipment, pollution abatement equipment, lifting equipment, pressure vessels, safety equipment, fire detection/protection equipment and other safety critical items through the site preventative and reactive maintenance programmes.
- 4.2.6 Utilities Manager
 - Carry out all routine inspections and tests on the fire detection and fire protection systems in accordance with legislative and insurance requirements.
- Training Manager 4.2.7
 - Co-ordinate the provision of training to all employees and contractors with regard to major . FOTIN accident prevention.
- 4.2.8 HR Manager
- ofcor Member of Strategic Response Team in the event of a Major Emergency.
- 4.2.9 Technical Services Director
 - Member of Strategic Response Team in the event of a Major Emergency.
- 4.2.10 Manufacturing Director
 - Member of Strategic Response Team in the event of a Major Emergency.
- 4.2.11 Shift Managers
 - Act as the Plant Incident Controller during a major emergency in accordance with the . Emergency Management Strategy, (Ref 16).

4.3 Identification of Training Needs

It is company procedure to ensure that all employees are appropriately trained and gualified in all aspects of their jobs and duties and a matrix outlining the safety and environmental taining requirements for each job type is maintained (Ref 6). EHS training needs are identified from risk assessments and/or on a competency basis. All training is competency based and competencies are inferred from job profiles. Job profiles are controlled documents and an individual profile is in place for each employee. From the Job profile and the EHS training requirements matrix, the individual EHS training requirements for each employee are identified in their individually tailored training programme. This system is described in more detail in the Training and Development

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Policy (Ref 7)

Safety and environmental training, both in-house and under the direction of qualified agencies, is arranged for employees on an on-going basis and training records are maintained. Departmental Managers, the EHS Director and the Safety & Loss Prevention Manager are responsible for identifying the training needs of all staff with respect to major accident prevention and for ensuring the adequacy of the training provided.

Training is provided in the following areas for the relevant staff members:

- Handling of hazardous chemicals.
- Operation of process equipment.
- Work permit systems.
- Use of fire extinguishers.
- Fork lift driving.
- Emergency response.
- First aid.
- Evacuation drills.
- Fire watch duty.
- Hazard evaluation techniques.
- Electrostatic hazard control.
- Process hazard analysis.
- clion purposes only any other use Chemical release/spillage response.
- Equipment Operation.
- Waste management.
- Change control.

5 Identification and Evaluation of Major Hazards

5.1 Scope and Definition:

In this document only those events that may lead to "serious danger to human health and/or the environment, immediate or delayed, inside or outside the establishment" (Ref 1) are considered.

5.2 **Hazard Identification**

A specific major accident scenario hazard review was carried out for the site in conjunction with Project Management Ltd, using the BMSC Hazard Identification and Risk Assessment Procedure (Ref 8) as a guide to categorisation of likelihood and consequence and to determine which scenarios warranted more detailed or quantitative risk assessment. SWIFT (Structured What If Technique) is identified and the main hazard identification technique to be employed.

This assessment adopted a 'cradle to grave' approach for risk assessment of all chemicals handled on site, which are included on the Seveso notification (Ref 12).

This approach is in accordance with the site's chemical risk assessment procedure (Ref 13).

All operations are reviewed for their potential to lead to the following general initiating events;

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- Small Leak (Where can leaks occur?).
- Large Spillage (Where can large spillages occur?).
- Undesired Reaction (How can an undesired reaction occur?).

These initiating events are in turn analysed to determine their potential to lead to the following events.

- Pool fires. The main hazard from a pool fire is exposure to thermal radiation.
- Jet fires. These are quite directional in nature, and relatively intense thermal radiation results in the vicinity of the jet.
- An un-confined (or partially confined) vapour cloud explosion (VCE).
- Flash fires.
- A physical explosion.
- A thermal explosion.
- A toxic release.
- An environmental release.

A more detailed description of how major accidents are identified is provided in the BMS Cruiserath Major HAZID document produced by Project Management Ltd (Ref 14)

5.2.1 Process Hazards Evaluation:

A full description of the procedures used to identify and evaluate potential hazards arising from specific processes or equipment is outlined in a Process Hazard Analysis Procedure (Ref 17). The BMS Cruiserath facility is a bulk manufacturing site only and there is no on site provision for process development, research and development or process scale up i.e. Kilo-lab or Pilot Plant studies. All processes that come to Cruiserath will have previously undergone process development on other BMS managed sites where such facility exists. The company shares all such information (i.e. copies of process HAZOPs carried out for other BMS sites, thermal hazard and dust characterisation and lessons learnt from processing experience elsewhere). Even with all of this information provided a site-specific process HAZOP is carried out for all new processes (or modifications to existing processes) for the Cruiserath site. Additional testing is organised through a competent laboratory where required. All major plant/equipment modifications, plant upgrade or new installations are also subject to rigorous change control and HAZOP.

5.3 Screening Risk Assessment

While all major accident scenarios are considered in the HAZID doc (Ref 14), a detailed quantitative consequence analysis with dispersion modeling etc, is only used for those scenarios which are determined as 'credible'. A screening philosophy has been employed which involves assessing, either semi-quantitatively or fully qualitatively, the likelihood of occurrence of each scenario. Based on this assessment and the stated risk acceptance criteria, those scenarios requiring full quantitative consequence assessment are identified. In some cases the less credible scenarios will also be considered for quantitative consequence assessment in order to establish a 'worst case' eventuality and to calibrate the screening risk assessment approach. Where this is done a rational is included in the quantitative risk assessment report (Ref 15).

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5.3.1 Likelihood Assessment

Considerations for the assessment of probability or likelihood are given in the Hazard Identification and Risk Assessment SOP, C-EHS-SOP-001 (Ref 8).

5.3.2 Qualitative Consequence Estimation

Considerations for the qualitative assessment of consequence are given in the Hazard Identification and Risk Assessment SOP, C-EHS-SOP-001 (Ref 8).

5.3.3 Quantitative Consequence Assessment

A number of major accident scenarios have been identified which could possibly lead to fire, explosion, toxic release or environmental release hazard. Those accident scenarios which are considered credible are recommended for quantitative consequence analysis i.e. consequence modeling. The outcome of this consequence assessment is presented in Project Management Ltd Document, 'BMS Cruiserath Seveso II, Major Accident Scenario Modeling and Risk Assessment." (Ref 15).

The consequence distances usually relate to the worst-case scenarios. They do not take into account any preventative or mitigating features (except bunding) which act to reduce the consequences estimated. Such measures include separation distances, detection systems and sprinkler/foam systems. Those items are considered only in the final risk assessment (Ref 15).

5.4 Risk Assessment:

A risk matrix has been developed for the site, based upon globally accepted and BMS management agreed risk acceptance criteria. This risk matrix, which is used to assess the risk of all hazardous aspects of environmental, health and safety management has been employed to assess the risk of each major accident scenario listed above. From the matrix, (given in Hazard Identification and Risk Assessment SOP Ref 8), the level of risk for each scenario is determined. The results of the major accident scenario risk assessment carried out using the risk matrix are detailed in Ref 15

5.5 Demonstration of Safety

The final risk assessment lists the controls that are in place for the prevention and mitigation of each possible major accident scenario identified. All necessary measures are taken to ensure safety.

Risk acceptability criteria have been expressed qualitatively to comply with best industry practice, legislation, codes of practice, or approved standards.

Approved codes of practice and standards set by bodies such as the American Society of Mechanical Engineers (ASME) and the British Standards Institution have provided another way of defining risk acceptability criteria. The relevant ASME or BS codes can be specified for particular systems to define an acceptable level of safety assurance.

In the absence of any clear code of practice or standard to define acceptable level of safety on particular systems, all necessary measures are be taken to reduce risk to an acceptable level.

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6 Operational Control

6.1 Inventory Control

6.1.1 Raw Materials & Products

The inventory of Seveso classified substances on site is managed by the site's materials management system, SAP.

All raw materials and products are given a unique material code on this system and classed according to their risk phrases.

The threshold limits allocated by the regulations to each hazard are built into SAP such that it can calculate the relevant ratios in each area and it can also sum these ratios for the relevant combinations of hazard classification i.e. 'Flammables, Highly Flammables and Oxidisers' and 'Toxics and Dangerous to the Environment'.

A report will be run from this system routinely to ensure that the site's inventory of hazardous substances does not exceed the limits set down in the regulations for a Lower Tier site.

A more detailed description of how this system works is given in the SAP system – High Level Requirements Specification for Waste Management and Seveso Reporting (Ref 10)

A description of how this report can be generated is given in 'Maintenance of Seveso Inventory Log' SOP (Ref 4).

6.1.2 Utilities Chemicals

There are some hazardous materials on site, which are not SAP managed, as they are not materials which are consumed. Examples include Syltherm, Glycol and Diesel. The full capacity of the dedicated tanks holding these materials will be assumed at all times.

6.1.3 Dilution Effects

Increase in the inventory of hazardous materials caused by the dilution of small amounts of 'toxic' material in a large amount of solvent during processing will be managed and assessed during the pre processing and process analysis stage (Ref 17). Depending on the combined amount of SAP managed consumables and non-consumables on site at the time, an appropriate limit will be set on the additional inventory of toxic material that can be generated by dilution effects during processing.

6.1.4 Seveso Inventory Log

An inventory log will be maintained, and updated regularly which combines the inventories of consumables, non-consumables and inventories generated from dilution in the manufacturing process in one report. A more detailed description of how inventories can be maintained at acceptable levels for a lower tier site is given as an appendix to the Seveso notification submitted to the Health and Safety Authority for the Cruiserath site (Ref 12).

6.2 Description of Plant, Equipment and Operation

An overview description of the plant is given in the Major Accident HAZID report (Ref 14) and a more detailed description of all plant, equipment and operations is given in the site's IPC Licence Application (Ref 9).

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6.3 Plant Protection and Control Systems

Several levels of control and safety protection are in place for all operations and processes across the site. These are described in more detail in the Process Safety Management Policy (Ref 18).

6.4 Operational Control - General

BMS Cruiserath establishes and maintains several procedures to ensure major accident risk control for all stages of lifecycle of the operation of the plant and processes. The safe operation of equipment and plant is controlled in equipment specific SOPs while safe operation of processes are covered in batch records.

All such SOPs are controlled documents and are available to all employees on the site's Master Document Database, but which can not be changed without going through documentation change control, (Ref 19).

Recommendations from process HAZOPs are included where applicable in the related log sheet. Systems are in place for controlling the risks at each of the following stages as appropriate:

6.4.1 Construction and Commissioning of plant, processes, equipment and facilities

The following systems and procedures are in place for control of major accident hazards during construction, commissioning and other abnormal activities.

- Change Control Procedure (Ref 20)
- Contractor Control Procedures (Re§35)^{*}
- Contractor Induction Training (Ref. 36)
- Excavation Permits (Ref 37)
- Line Breaking Permits (Ref 38)
- Confined Space Entry Permits (Ref 39)
- Hot Work Permits (Ref 38)
- Process Hazard Analysis Procedure (Ref 17)
- EHS Prestart up checklist procedure (Ref 41)

6.4.2 Operation of Plant and Processes

- Equipment vendor manuals are available and written operating procedures are in place for all pieces of operating equipment.
- As Cruiserath is only a bulk manufacture facility and has no scale up and/or developmental facility any manufacturing process adopted on site comes from another BMSC facility. This is managed under defined and documented Technical Transfer procedures, (Ref 42).
- 'Batch Record' is the name given to a process procedure. Not only does the batch record detail the steps necessary for manufacture of a particular product but it also highlights any major hazards potential, a summary of the MSDS information for each chemical involved in the process and any special emergency response procedures associated with the process. Batch records are controlled documents and as such undergo a rigorous review and approval process both when they are newly issued and if any part is modified, (Ref 43).
- Training is provided in equipment operation and in batch processing.

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- The plant is highly automated and the process control system, Delta V, is a phase logic DCS system. Recipes for each process are built by combining a variety of generic processing 'phases'. Phase specific interlocks are written into the phase logic but equipment specific interlocks of all integrity levels are defined in cause and effect matrices which are available for each equipment system and which are controlled documents, (Ref 44).
- A Line Breaking Permit Procedure is in place and applies to any cutting or disconnection of hard piped flanged lines including campaign manifold change over, (Ref 38).
- A detailed Tanker Unloading Procedure is in place, (Ref 45). All tanker-unloading operations are supervised by a BMS Cruiserath staff member.
- Security access is required at all levels of reading, writing, operation and changing to the DCS and safety integrity PLC software programming, (Ref 46).
- Several layers of engineering controls are built in to the design of the plant and equipment (Ref 2)

6.4.3 Maintenance

- The preventative maintenance programme is managed by 'Maximo' software system. Work orders raised on Maximo automatically prompt the maintenance department if a special permit is required or at a minimum requires that a safe work plan is filled out. A set of 'critical instrument' criteria has been development which will feed into Maximo and will prioritise preventative maintenance of instruments deemed 'critical' either in terms of safety, IPC licence compliance, GMP compliance or Production.
- Permit to Work System: Separate permit procedures are in place for Hot Work, Line Breaking, Confined Space Entry, Working at Heights, Electrical Work, Excavation, Use of Radioactive Sources and Fire Protection System Impairment. A miscellaneous 'Safe Work Permit' system is also in place to cover any unanticipated hazardous activity, which is not otherwise covered by any of the usual permit procedures.
- The routine maintenance of the fire detection system, the fire protection system and the safety showers is contracted out to specialist third parties. These contractors are selected following standard contractor pre-qualification procedures and the contracts are managed by the Utilities manager.
- An inspection programme for boilers and pressure vessels, carried out by 3rd party insurers, is in place and built into Maximo
- A decommissioning procedure is also in place.

7 Management of Change

A comprehensive change control system (Ref 3) is in place and co-ordinated by the QA department which not only covers changes to plant equipment and processes but also any changes to layout, software, inventory, documentation and management systems.

All such changes are assessed by the appropriate personnel (pre-defined for each department) and all necessary pre-implementation (e.g. carry out HAZOP or implement controls) and post-implementation actions (e.g update P&IDs) are identified. The pre-implementation actions have to be signed off as complete before the change can be implemented and the post-implementation changes signed off as complete before the change control can be closed out.

All changes must be reviewed by EHS and the EHS assessment of change is done by nominated Valid only on the date of printing: 26/Oct/2006, 16:35

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competent personnel in accordance with the EHS Change Assessment Procedure (Ref 20). This procedure lists the questions that should be asked or things that should be considered for each individual change type.

A change control committee is in place comprising of members of all revelent departments including EHS. The function of this committee, which meets regularly, is to develop and review any new or outstanding change controls and to review and update the change control procedure as necessary.

Finally there is a change control steering group which is made up of senior management and headed up by the General Manager. Anyone breaching site change control protocol must answer to this group at their monthly meeting.

8 Planning for Emergencies

Cruiserath has in place an Emergency Management Strategy (Ref 16). The Emergency Management Strategy describes in detail the responsibilities of all personnel, the command structures and the information required during an emergency at the plant. It also gives an overview of the structures in place for management of emergencies.

The mechanism for communication between the Emergency Response Team and the Incident Controller, between the Incident Controller and the Main Site Controller and between the Main Site Controller and the outside world (emergency Services, relatives, neighbours and the press) is all detailed in the strategy document.

Referenced in the Emergency Management Strategy are the detailed response procedures appropriate for each foreseeable emergency and these include, obviously those scenarios identified in the hazard identification section of the MAPP. The range of 'general' emergencies ofcopy considered include:

- Fires
- Explosion
- **Chemical Spillage**
- **Environmental Release**
- **Toxic Release**
- Gas Leakage.
- Injury

More detailed emergency response procedures are in place for responding to those major accident scenarios identified. These are:

Emergency Response Procedures - ERT (Ref 22)

Emergency Response Procedures – Security (Ref 23)

Consent

Emergency Response Procedures - Fire Wardens (Ref 24)

Major Emergency Response Procedure (Ref 25)

All personnel on site are trained in the basic fire safety awareness and use of fire extinguishers. Any personnel working with hazardous chemicals receive training in spill control procedures.

Several levels of Emergency Response are defined in the Emergency Management Strategy. At any time the level of emergency response provided will depend on the hazards on site and the availability of trained ERT members.

A trained dedicated Emergency Response Team comprising mainly of manufacturing and Valid only on the date of printing: 26/Oct/2006, 16:35

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technical services technicians, shift chemists and maintenance technicians will be provided. Emergency response team members will be trained in, fire watch duty, search and rescue, fire alarm investigation, fire fighting and chemical spill control. A more detailed description of the training provided to the ERT is provided in the ERT Training Requirements SOP (Ref 26)

In the event of an emergency, the ERT are directed fom the Incident Control Centre by the Incident Controller who is the Site Shift Manager. The Site Shift Manager is the 'person in charge' of the entire site outside of normal working hours and will liase with the emergency services and/or call in other senior managers as necessary in the event of an emergency.

A Strategic Emergency Response Team comprising of the key high-level management personnel is also in place. It is the function of this committee to review the emergency plan periodically and to assist the Main Site Controller (who is the General Manager) in making critical decisions in the event of a major emergency.

Regular Drills are held on site to test the performance of the ERT and the effectiveness of the emergency response procedures. These drills are co-ordinated by the Safety and Loss Prevention Manager and will, periodically include involvement of the external emergency services e.g. Dublin Fire Brigade.

9 Monitoring Performance

As the EHS management process map (Ref 27) indicates, the area risk assessments, the EHS objectives and targets and the occupational health/industrial hygiene philosophy gives rise to the EHS management programme which is covered on the process map as System Monitoring and EHS Planning and Scheduling. This is also a requirement of ISO and is essentially a schedule of EHS monitoring that is required in order to confirm that the controls listed in all risk assessments are maintained and that the containment specs are being met.

All accidents, environmental incidents, and near misses are reported and investigated in accordance with the site's Accident/Incident/Near-Miss Reporting and Investigation Procedure (Ref 30). A root cause analysis is undertaken in each instance and appropriate corrective actions identified as required. These corrective actions may include a requirement to update such documents as the Safety Statement, the MAPP, the Emergency Management Strategy or individual Emergency Response Procedures. An update of the Major Accident HAZID may also be identified as a requirement.

For breaches in documented EHS safety procedure, failure of EHS critical equipment or reporting of unsafe conditions a Non-Conformance Procedure is in place (Ref 31). Non-conformances are issued to the responsible manager who must put an action plan in place to ensure that the non-conformance is addressed and can not reoccur.

All high integrity trips and interlocks and independent safety protective devices (e.g. relief valves) are subject to rigorous preventative maintenance routines. The frequency of testing/inspection of critical safety controls is either driven by legislation of specific standards or by the assumed failure frequency (which often assumes a certain testing frequency). Failure frequencies of critical safety equipment items are logged and trended by 'Maximo', the preventative maintenance software system, and so this flags if the failure frequency of any particular item starts to exceed the expected or assumed failure frequency in risk assessments.

Under the Pressure Equipment Directive, all pressure systems are subject to routine 3rd party inspections. All vessels that contain hazardous chemicals are tested for wall thickness and indication of stress or fatigue using non-destructive x-ray testing. This is carried out every 3-5 years.

Under the conditions of the IPC licence, bund, monitoring and ground water borehole monitoring Valid only on the date of printing: 26/Oct/2006, 16:35

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is carried out on an annual basis. Continuous monitoring of the surface water, wastewater and incinerator emissions is in place, the results of which are continuously monitored in the environmental systems control room. The results of this environmental monitoring must be compiled every quarter and submitted to the Environmental Protection Agency as the Annual Environmental Report.

A 3 yearly live test of the Major Emergency Response Procedure is also planned.

A debriefing session with all personnel involved is held after any drill and a report generated outlining an assessment of how the drill went and recommending any corrective actions that need to be taken in order to improve the emergency management/response provision.

10 Audit & Review

A detailed auditing schedule and programme is put together at the beginning of every year. On an annual basis, a very detailed internal Environmental, Health and Safety audit is carried out for every area on site. This comprehensive EHS audit is a check of all the controls listed in all of the various EHS risk assessments for the areas i.e.

> 5 for

- The ISO 18001 risk assessments.
- The ISO 14001 environmental impacts and aspects risk assessments.
- The MAPP risk assessments.
- .
- .

Process and Equipment HAZQPShowner the second ance with the second ance The audits are carried out by the EHS department in conjunction with the relevant area manager in accordance with the EHS audit procedure (Ref 28). Actions arising from the audits are prioritised for immediate action or more long term action as appropriate and are all assigned to a named person with a close out date for completion of the action agreed between the auditors and the actioned individual.

All of these action items are logged in a 'deviation' database management system. HAZOP actions, accident/incident investigation actions or even actions arising from any 'nonconformance' observations made outside of the more formal structure of these systems, are all logged in the same 'deviation' database and the system automatically flags to the auditor what actions are outstanding or are past their due date for close-out.

Audits may often reveal hazards not previously considered in any of the area risk assessments listed above or may indicate that the failure frequency predicted or the consequence predicted needs to be revised. In this case a review/update of the risk assessment is actioned which may in turn yield an unacceptable level risk and so require that additional controls are needed or that the risk is reduced through inventory control.

An annual management review of the entire EHS management system is undertaken. In this review, results from audits, risk assessments, industrial hygiene monitoring, accident/incident investigations, emergency drills and maintenance inspections will be considered and the appropriate section of the management system updated if required. As one of the key policy documents which forms part of the overall site EHS management system, the MAPP (and the structures described therein) is subject to this annual review and is updated as necessary. The EHS management review process is described more fully in the EHS management review procedure.

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11 References

- EC (Control of Major Accident Hazards Involving Dangerous Substances) Regulations, 2000. S.I. No, 476 of 2000.
- 2. C-EHS-POL-002, Safety Statement
- 3. C-QUA-POL-001 Change Control Policy
- 4. C-EHS-SOP-060, Maintenance of Seveso Inventory Procedure
- 5. C-HR-RGT-001, BMSC Organisational Chart
- 6. C-EHS-RGT-003, EHS Training Matrix
- 7. C-HR-POL-001, Training and Development Policy.
- 8. C-EHS-SOP-001, Hazard Identification and Risk Assessment
- 9. Integrated Pollution Control Licence Application, Bristol-Myers Squibb, Cruiserath, Mulhuddart, Dublin 15, Ireland.
- 10. Cruiserath Waste Management & Seveso Regulations SAP Design Specifications, Doc No 2003-119J-DS
- 11. C-EHS-SOP-012, Permit to Work Procedure
- 12. H.S.A. Seveso Notification for BMS Cruiserath
- 13. C-EHS-SOP-056, Chemical Risk Assessment Procedure
- 14. Major Accident HAZID, PM Ltd Doc Ref 01058-23-RP-001
- 15. Major Accident Scenario Modelling and Risk Assessment, PM Doc Ref 010568-23-RP-002
- 16. C-EHS-POL-005, Emergency Operations Plan
- 17. C-EHS-SOP-081, Process Hazard Analysis Procedure
- 18. C-EHS-SOP-002, HAZOP
- 19. C-QUA-SOP-003, Documentation Change Control Procedure
- 20. C-QUA-SOP-002. Change Control Procedure
- 21. C-EHS-SOP-048, EHS Change Assessment Procedure
- 22. C-EHS-SOP-036 Emergency Response Procedures ERT.
- 23. C-EHS-SOP-033, Emergency Response Procedures Security.
- 24. C-EHS-SOP-035, Emergency Response Procedures Fire Wardens.
- 25. C-EHS-SOP-040, Emergency Response Procedure Strategic Management
- 26. C-EHS-SOP-049, ERT Training Requirements Procedure
- 27. C-EHS-MAP-001, Safety Management System
- 28. C-EHS-SOP-024, EHS Audit Procedure
- 29. C-EHS-SOP-025, EHS Management Review Procedure
- 30. C-EHS-SOP-022, Accident/Incident/Near Miss Reporting and Investigation procedure
- 31. C-EHS-SOP-023, EHS Non-Conformance Procedure
- 32. BMS EHS Corporate Standard, Process Safety Management, Http://home.bms.com/EHStech standards/techstdshtm
- 33. C-HR-POL-006, BMSC Recruitment and Selection Policy
- 34. C-HR-SOP-017, Performance Partnership Programme. Valid only on the date of printing: 26/Oct/2006, 16:35

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- 35. C-EHS-SOP-027, Contractor Safety Management Procedure
- 36. C-EHS-TRA-002, EHS Induction Training Manual Level 2
- 37. C-EHS-SOP-018, Excavation Permit Procedure.
- 38. C-EHS-SOP-015, Line Breaking Procedure
- 39. C-EHS-SOP-017, Confined Space Permit Procedures
- 40. C-EHS-SOP-016, Hot Work Permit Procedures.
- 41. C-EHS-SOP-062, EHS Pre-startup checklist procedure.
- 42. C-TOG-MAP-001, TOG Technology Transfer Map
- 43. C-QUA-SOP-005, Review and Approval of Controlled Documents
- 44. C-AIM-MAP-001, IM Automation Systems
- 45. C-TS-SOP-005, Tanker Unloading Fresh Solvent and Chemicals
- 46. C-AIM-SOP-001, DCS AMS & MTS Security Configuration and Management
- 47. C-ENG-SOP-021, Maximo Work Order Management
- 48. C-ENG-SOP-022, Maximo Planned Work Schedules Creation
- 49. C-ENG-SOP-023, Maximo Equipment and Inventory Registration

12 Abbreviations/ Glossary

AIM	Automation and Information Management American Society for Mechanical Engineers
	American Society for Mechanical Engineers
3MSC	
	Bristol Myers-Squibb Cruiserath
3S	British Standard
DCS	Distributed Control System
EC	European Community
EHS	Environmental health and safety department
ERT	Emergency Response Team
GMP	Good Manufacturing Practice
IAZID	Hazard Identification
IAZOP	Hazard and Operability Study
IR	Human resources department
PC	Integrated Pollution Control
so	International Standards Organisation
ЛАРР	Major Accident Prevention Policy
PM Ltd	Project Management Limited
P&IDs	Process and Instrumentation Diagrams
PLC	Programmable Logic Controller

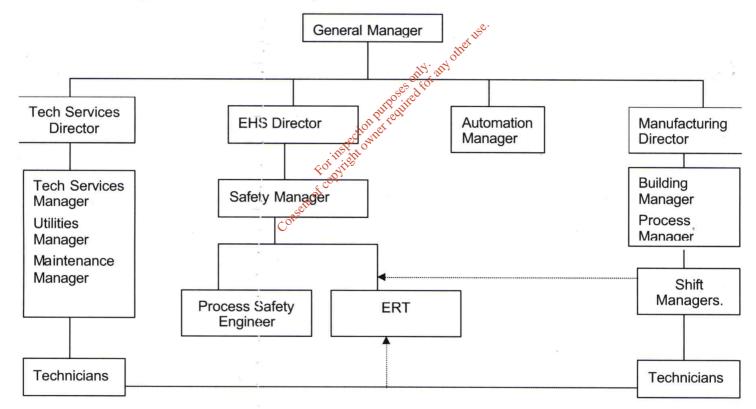
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Phrase	Explanation
POL	Policy
QA	Quality Assurance
Ref	Reference
SAP	Software Application Programme
SOP	Standard operating procedure
Tech	Technical
VCE	Vapour Cloud Explosion

13 Appendices

1. Organisational Structure – Major Accident Prevention



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