

**EMERGENCY PLAN**

EMERGENCY PLAN

Written by:	Reviewed by:	Approved by:
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CONTENTS

1.	BASIC INFORMATION	1
1.1	Industrial Activity -----	1
1.2	Location and Access -----	1
1.3	Fire Service -----	2
1.4	Health Care -----	2
1.5	Useful Contact Numbers -----	2
1.6	Copies of the Emergency Plan -----	2
2.	OBJECTIVES OF THE EMERGENCY PLAN	3
2.1	Aims -----	3
2.2	Emergency Categories -----	3
2.3	Considerations -----	4
2.4	Abbreviations -----	4
3.	MANAGEMENT OF THE EMERGENCY	5
3.1	Emergency Flow -----	5
3.2	Organisation and role of Intervention Personnel -----	5
3.3	Emergency exits and recommended escape routes -----	6
3.4	Assembly Point -----	6
3.4.1	Definition -----	6
3.4.2	Location -----	6
3.5	Alarm Signals -----	6
3.5.1	Fire Panel Fault Signal -----	6
3.5.2	Pre-Alarm Warning Signal -----	6
3.5.3	Evacuation Signal -----	6
3.6	Emergency Personal Protective Equipment -----	7
3.7	Material Safety Data Sheets (MSDS) -----	7
3.8	Explosive Atmosphere -----	7
4.	ACTIONS IN CASE OF FIRE/EXPLOSION/SPILL	8
4.1	Actions during normal hours (Mon – Fri 08:00 – 17:00) -----	9
4.1.1	Procedure for the person discovering the Spill -----	9
4.1.2	Procedure for the person discovering the Explosion/Fire -----	10
4.1.3	Procedure for the Security Guard (SG) -----	11
4.1.4	Procedure for the Head of Emergency (HE) -----	12
4.1.5	Procedure for the Head of Intervention (HI) -----	13
4.1.6	Procedure for the Emergency Coordinator (EC) -----	14
4.1.7	Procedure for the Cordon Officer (CO) -----	15
4.1.8	Procedure for the First Aid and Intervention Teams (FATC, FAT, TC, IT) -----	16
4.1.9	Procedure for the Fire Warden -----	17
4.1.10	Procedure for all other personnel -----	19
4.2	Actions outside normal hours (Mon – Fri 17:00 – 08:00 and Production Weekends) -----	20

4.2.1	Procedure for the person discovering the emergency -----	20
4.2.2	Procedure for the Security Guard (SG) -----	21
4.2.3	Procedure for the Acting Head of Intervention (AHI) -----	22
4.3	Actions during weekends and shutdowns (with Engineering personnel on site)-----	23
4.4	Actions during weekends and shutdowns (without Engineering personnel on site)-----	23
4.5	Actions for lone workers, especially during out of office hours or shutdowns-----	24
5.	TELEPHONED BOMB THREAT OR SUSPECT PACKAGE	24
5.1	Telephoned Bomb Threat-----	24
5.2	Suspect Package -----	24
6.	ACTIONS TO BE TAKEN IN CASES OF PERSONAL INJURY	25
7.	END OF THE EMERGENCY	26
8.	REPORTING AFTER THE EMERGENCY	26
9.	ANNEXES	27

1. BASIC INFORMATION

1.1 Industrial Activity

Medichem Manufacturing (Malta) Ltd. (hereinafter, Medichem) is a manufacturer of active ingredients for the pharmaceutical industry, through four distinct production areas:

- Active Pharmaceutical Ingredients (API) Production Plant
- Pilot Plant and kilo-Lab
- Physical Treatment Plant
- High Potency Active Ingredients (HPAPI) Unit

Combino Pharm (Malta) Ltd. (hereinafter, Combino) is a manufacturer of pharmaceutical, non-sterile solid final dosage forms (FDF) tablets and capsules.

The following areas support the manufacturing processes:

Medichem	Combino
Flammable solvents tank farm	LPG installation (shared)
Internal and External Warehouses	Internal Warehouse
Internal and External Technical Areas	Internal and External Technical Areas
Engineering Workshop	Engineering Workshop
Wastewater Treatment Plant (shared)	-
-	QC Laboratory (shared)
R&D Laboratory	-
Office Areas	Office Areas

1.2 Location and Access

Medichem and Combino are located in the Hal Far Industrial Estate, limits of Birżebbuġa, Malta (GPS coordinates: 35.82°N 14.51°E). The facilities are located between next to Pharos (ex Arrow/Teva/Actavis) . Access is via the roads linking the Industrial Estate to the towns of Gudja and Birżebbuġa.

From Gudja, follow the signs to Hal Far. Enter the Hal Far Industrial Estate from the entrance on the right of the junction which leads to the Employment & Training Centre. Drive past the Quarter Mile Race Track (on your left) towards Brandstätter (Playmobil), then turning left and drive all the way to the factory next to the last.

From Birżebbuġa, follow the road to Ghar Hasan, then enter the Hal Far Industrial Estate and drive past the array of factories leading to a cross road with Combino on your left.

1.3 Fire Service

The nearest professional fire station is the Civil Protection Department Hal Far Fire Station located at a distance of about 500 m from the site. The estimated time of response in the case of an emergency is 5 to 10 minutes.

1.4 Health Care

In the case of serious injuries, an ambulance is to be called through the 112 service, which will take the casualty/casualties to **Mater Dei Hospital** on Birkirkara Bypass. To get there, drive past the Airport, take direction to Valletta, then take direction to Sliema. Before arriving take direction to Birkirkara and subsequently follow the signs to Mater Dei Hospital.

For significant injuries which do not require an ambulance, the nearest hospital is **Saint James Hospital**, located at Triq il-Hotba, Zejtun. The quickest route is through Gudja, towards Tal-Barrani, past the perimeter of Bulebel Industrial Estate and then following the signs to Żabbar Centre. Adequate signs in Żabbar lead to Saint James Hospital.

For minor injuries, the nearest Health Centre is in Paola. It is located at Antoine de Paule Square, next to the Post Office, opposite the church.

1.5 Useful Contact Numbers

Annex II shows a list of useful contact numbers in case of an emergency.

1.6 Copies of the Emergency Plan

Department	Location	Copy Number
Engineering	EPHS Manager	ORIGINAL
Administration Laboratories	Medichem Office Area (Fax/Printers Area, First Floor)	1
	Combino Entrance (Fire Repeater Panel)	2
Operations	Medichem Pilot Plant Control Room	3
	Medichem Internal Warehouse Office	4
	Combino Production Office	5
	Combino Warehouse Office	6
HPAPI Unit	HPAPI R&D Laboratory	7
Others	Guard Room	8

2. OBJECTIVES OF THE EMERGENCY PLAN

2.1 Aims

The basic objective of an Emergency Plan is to inform the organisation of the available technical and human resources to face the various states of emergency which may occur.

The Emergency Plan establishes a procedure to be followed in an emergency situation, defining the rules, organisational structure, communication, responsibilities and the procedures to be followed by each function within the structure, in order to face the incident and the related consequences in an organised manner, with the following aims:

- Contain and control the incident which caused the emergency;
- Safeguard human life;
- Minimize damage to the environment;
- Minimize damage to the installation.

The Emergency Plan applies to all personnel on site, whether they are company employees, visitors or contracted personnel. It will be revised whenever there are significant changes to the operations or new legal requirements. The annexes can be revised separately whenever required, indicating the revision date.

2.2 Emergency Categories

Category 1: An emergency situation which is not expected to have an effect outside of the installation and which can be tackled by the organisation's own personnel and equipment in a short period of time.

Category 2: An emergency situation which is expected to result in casualties and severe damage to the installation. The external repercussions will be limited to light damage or adverse environmental effects in limited zones.

Category 3: An emergency situation which is expected to result in casualties and severe damage to the installation. The external repercussions will cause severe damage or adverse environmental effects in extensive zones external to the installation.

2.3 Considerations

The following considerations must be taken into account in order to minimise emergency reaction time:

- a) Absence of obstacles in front of the emergency and First Aid equipment (First Aid kits, emergency showers, spill kits);
- b) Adequate signage for the different types of emergency and First Aid equipment;
- c) Adequately maintained equipment and facilities.

In order to facilitate rapid evacuation and reduce the spread of panic during the evacuation process, the following conditions must be met:

- a) Absence of obstacles in the evacuation routes and exits;
- b) Sufficient illumination in evacuation routes;
- c) Adequately maintained signage of the different evacuation routes.

2.4 Abbreviations

Abbreviation	Meaning
HE	Head of Emergency
HI	Head of Intervention
AHI	Acting Head of Intervention
EC	Emergency Coordinator
CO	Cordon Officer
FATC	First Aid Team Coordinator
FAT	First Aid Team (all trained first aiders)
IT	Intervention Team
TC	Technical Coordinator
CC	Centre of Communication (Guard Room)

3. MANAGEMENT OF THE EMERGENCY

3.1 Emergency Flow

Annex III shows a process flow diagram in a typical emergency situation, outlining the main functions and communication links between the key people, leading to the end of the emergency.

3.2 Organisation and role of Intervention Personnel

Although during an emergency the cooperation of all employees is expected, the organisation has set up a team to optimize effectiveness in such situations.

The Organisation of the Emergency Team is shown in Annex IV.

Picture 1: Organization of Emergency Team

- **Head of Emergency:** The HE will be responsible for the co-ordination of all emergency actions and procedures on site. He/she holds the highest position of responsibility. The constant presence of the HE (or the next person in the chain of command below, except outside of normal hours) is mandatory throughout the development of any emergency situation. This means that as soon as an emergency situation is discovered, it will be extremely important to locate the **HE**.
- **Cordon Officer:** The CO will be responsible to carry out the head count and to control access and egress into the emergency area.
- **Head of Intervention:** The HI will be responsible to communicate with the Fire Wardens and provide all information to the HE such as status of emergency, what material is being used in the production area, what fire hazards could be present, etc. He/she will also communicate with the Technical Coordinator on what systems need to be closed down, etc.
- **Emergency Co-ordinator:** The EC is to assist the HE in co-ordinating internal and external emergency response. He/She will be responsible to communicate with external parties such as neighbouring plants and upon request by the HE, the EC will request help from the external emergency assistance (ambulance, fire service, police etc). Upon arrival of the emergency services the EC will be responsible to provide all necessary information such as MSDS sheets, plans, etc.
- **Fire Wardens:** The FWs are responsible to inspect their assigned area for any hazard and communicate with the HI providing feedback on the status of emergency (if possible and if within their area), or ensure that personnel within his/her area are acting as required by the emergency plan.
- **Technical Co-ordinators:** Responsible to manage utilities during an emergency including the switching on of the Fire Fighting system, switching off of electricity, gas or any other utilities which may result in additional hazard.
- **First Aiders Co-ordinators:** Responsible to assist during an emergency in case of any injuries or casualties.

3.3 Emergency exits and recommended escape routes

The location of emergency exits and the recommended escape routes to be taken by all personnel when moving to the Assembly Point, or in the case of total evacuation, is shown in **Annex V**. It is to be noted that so far as reasonably practicable, external routes are preferred, always preferring the route which is farthest from the accident/emergency zone, even if this means taking a longer route (for example, in the case of a fire in the Medichem external warehouse, a person evacuating from the Engineering Workshop should take the route in the direction of the boiler room, leading to the front of the office building).

Annex VI shows a number of emergency signs which are used to facilitate evacuation.

3.4 Assembly Point

3.4.1 Definition

The Assembly Point is defined as the place of safe condition. The effectiveness of the evacuation can be verified at the Assembly Point by means of a simple head count carried out by the Heads of Department, reported to the Cordon Officer. If this location is not in safe conditions due to the emergency itself, the Head of Emergency will communicate the location of the new Assembly Point.

3.4.2 Location

The Assembly Point is located next to the Guard Room, just inside the facilities. This area is located at a reasonable distance from the areas where emergency situations may arise. Personnel standing at the Assembly Point must not hinder the circulation of external emergency vehicles.

3.5 Alarm Signals

3.5.1 Fire Panel Fault Signal

Faults in the fire system trigger an alarm on the Fire Panel installed in the Guard Room. At the sounding of this alarm, the Security Guard will follow the procedure shown on page 9.

3.5.2 Pre-Alarm Warning Signal

The pre-alarm warning, consisting of a discontinuous siren tone, means that the other site is in evacuation. Personnel are to follow procedure on pg 19.

3.5.3 Evacuation Signal

The evacuation signal consists of a continuous siren tone. The activation of this alarm can be activated either via break-glass units, or after 3 minutes have passed after activation of 1 detector, or from the activation of more than 1 detector, or activated manually from the Fire Control Panel by pressing and holding the evacuation button for at least 10 seconds at the request of the HE or HI.

3.6 Emergency Personal Protective Equipment

In the Guard Room, to the right of the Fire Control Panel, there is a wall cabinet containing one full face mask complete with combined filters, two pairs of chemical gloves, two PVC aprons and two Tychem[®] full encapsulating suits. This personal protective equipment can be used in **exceptional** circumstances, in cases where it will not be possible for a user to use his/her own PPE, or to support a second user (**remember to always deal with an emergency in pairs**).

3.7 Material Safety Data Sheets (MSDS)

The above mentioned cabinet also contains a list of all the materials present on site. Paper copies of the MSDS's for these substances are filed in the Guard Room. It is the responsibility of the EPHS manager to review and update this file either upon introduction of a new hazardous material on site, or during the annual review.

3.8 Explosive Atmosphere

Areas which have a risk of forming explosive atmosphere are indicated in Annex XII. In these areas employees are requested to wear appropriate PPE and only ATEX equipment is allowed inside. Special control measures are indicated in different operating procedures to control the risk of Fire and Explosion during operation.

4. ACTIONS IN CASE OF FIRE/EXPLOSION/SPILL

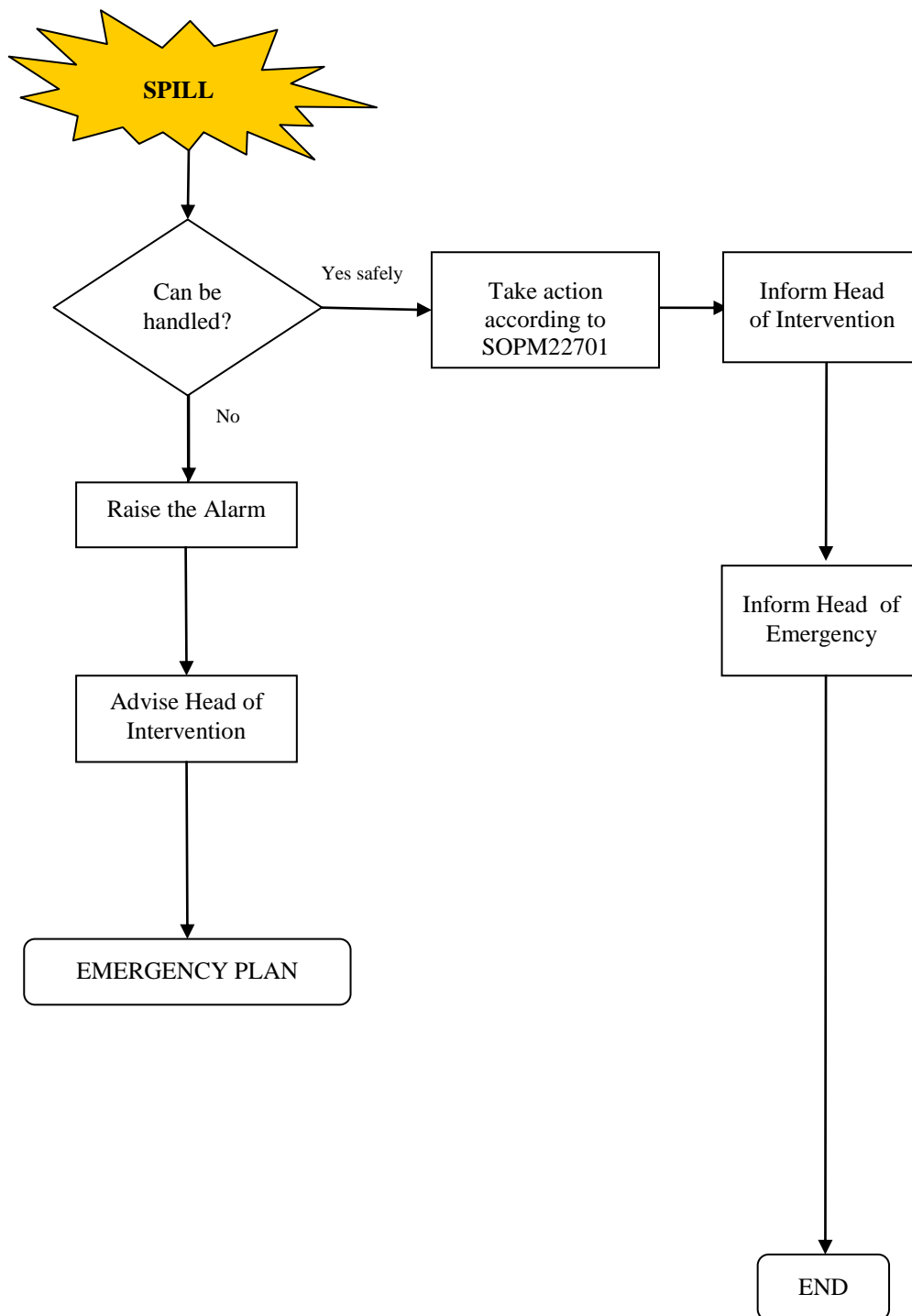


FIRE /EXPLOSION/SPILL

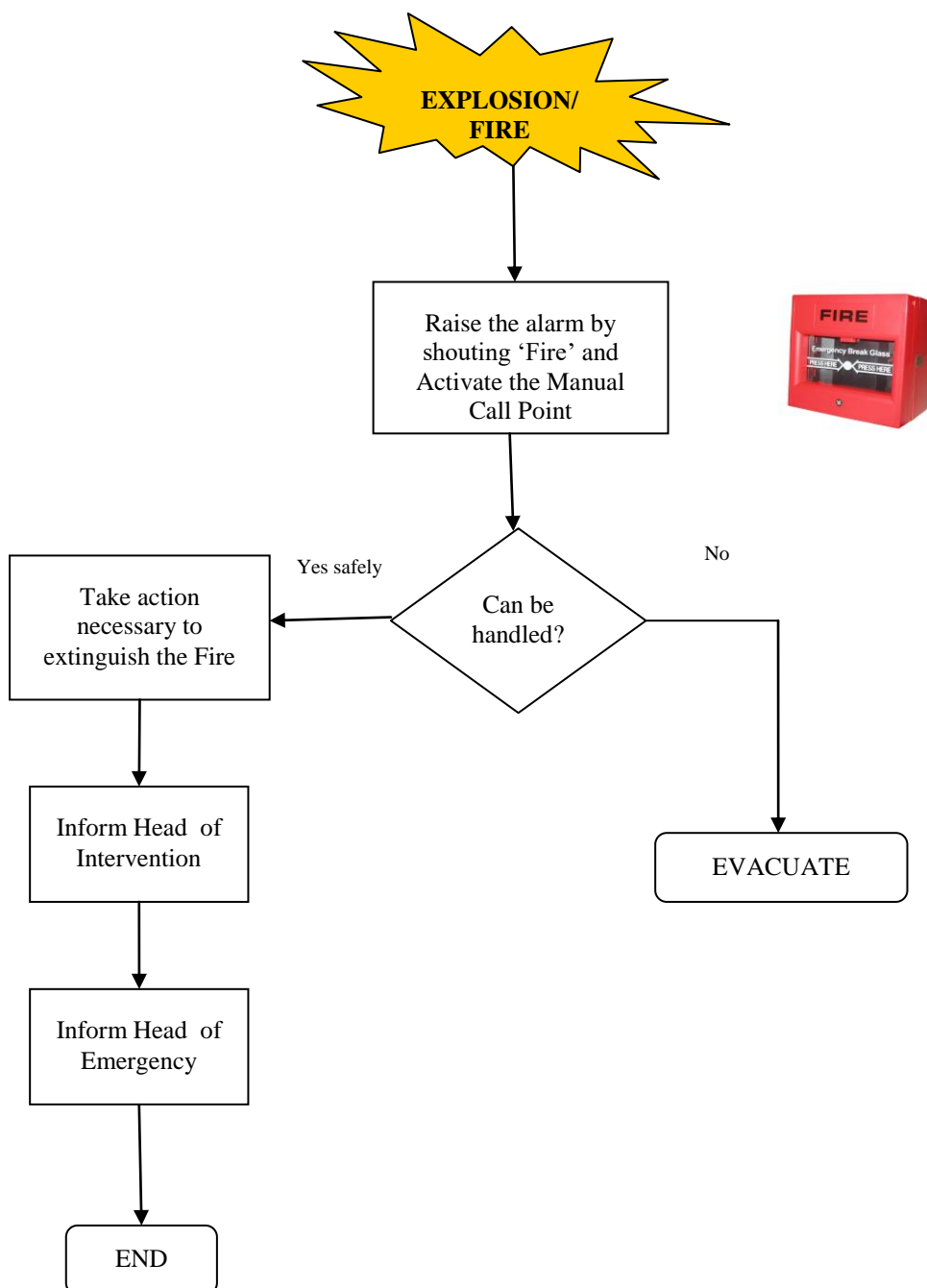


4.1 Actions during normal hours (Mon – Fri 08:00 – 17:00)

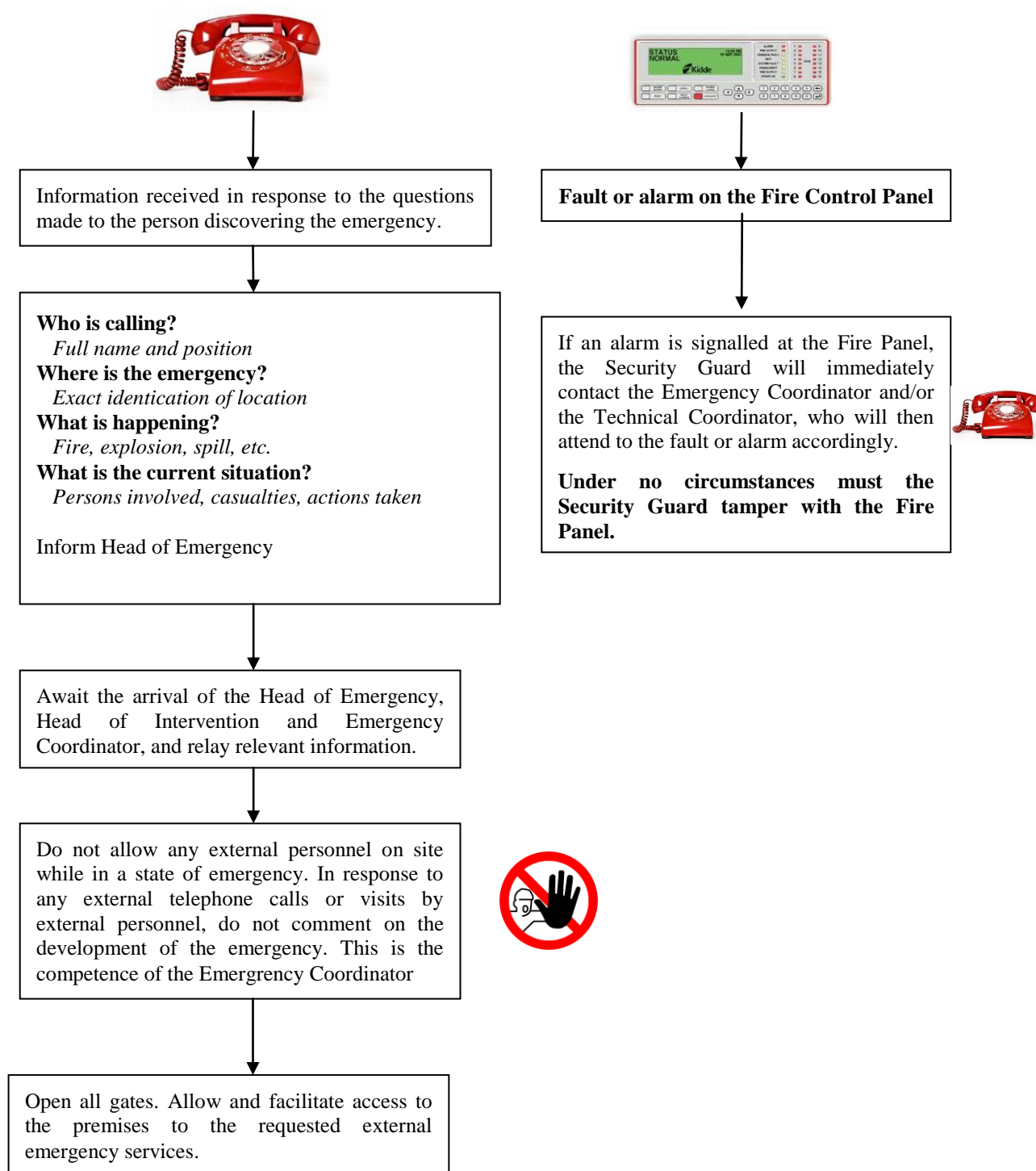
4.1.1 Procedure for the person discovering the Spill



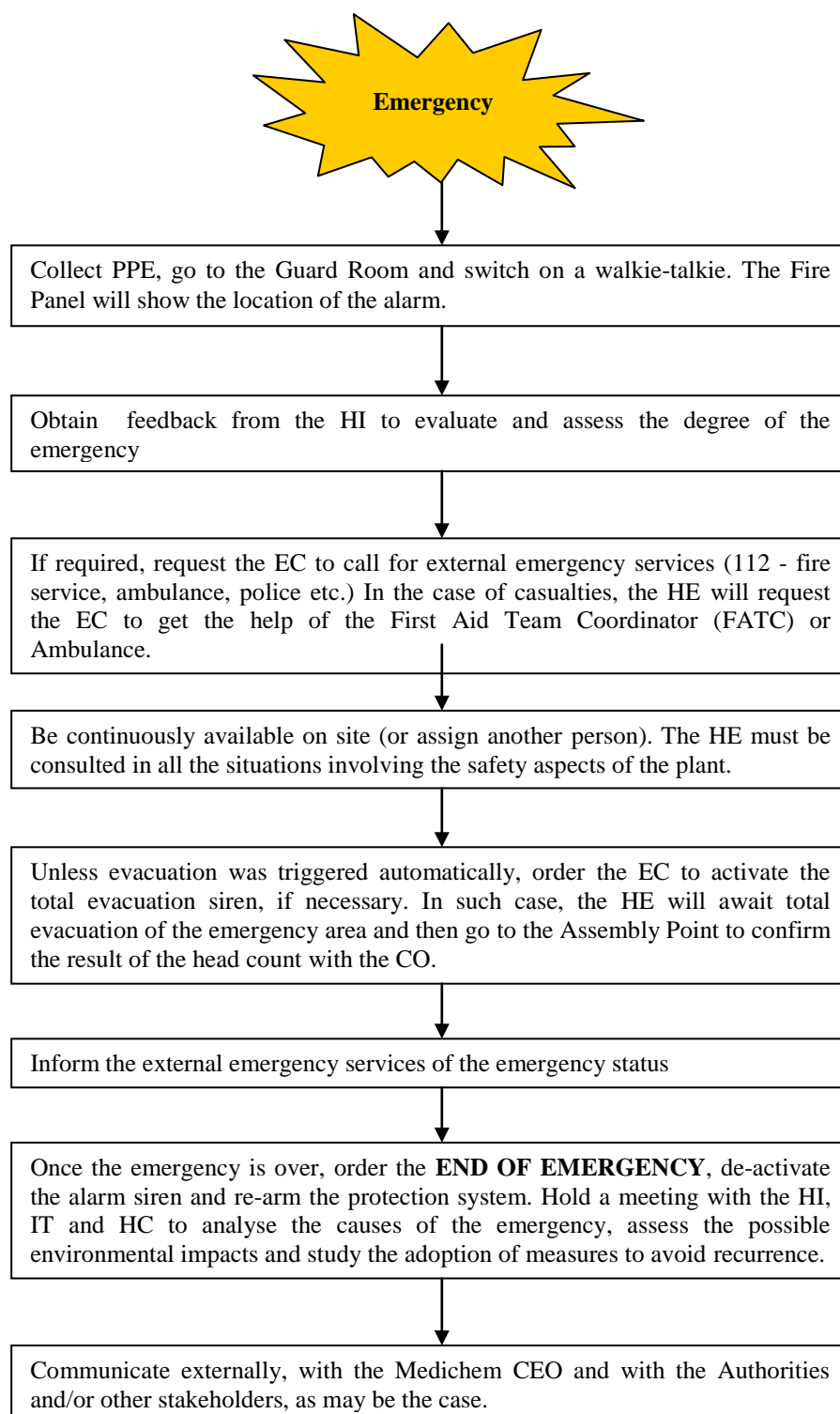
4.1.2 Procedure for the person discovering the Explosion/Fire



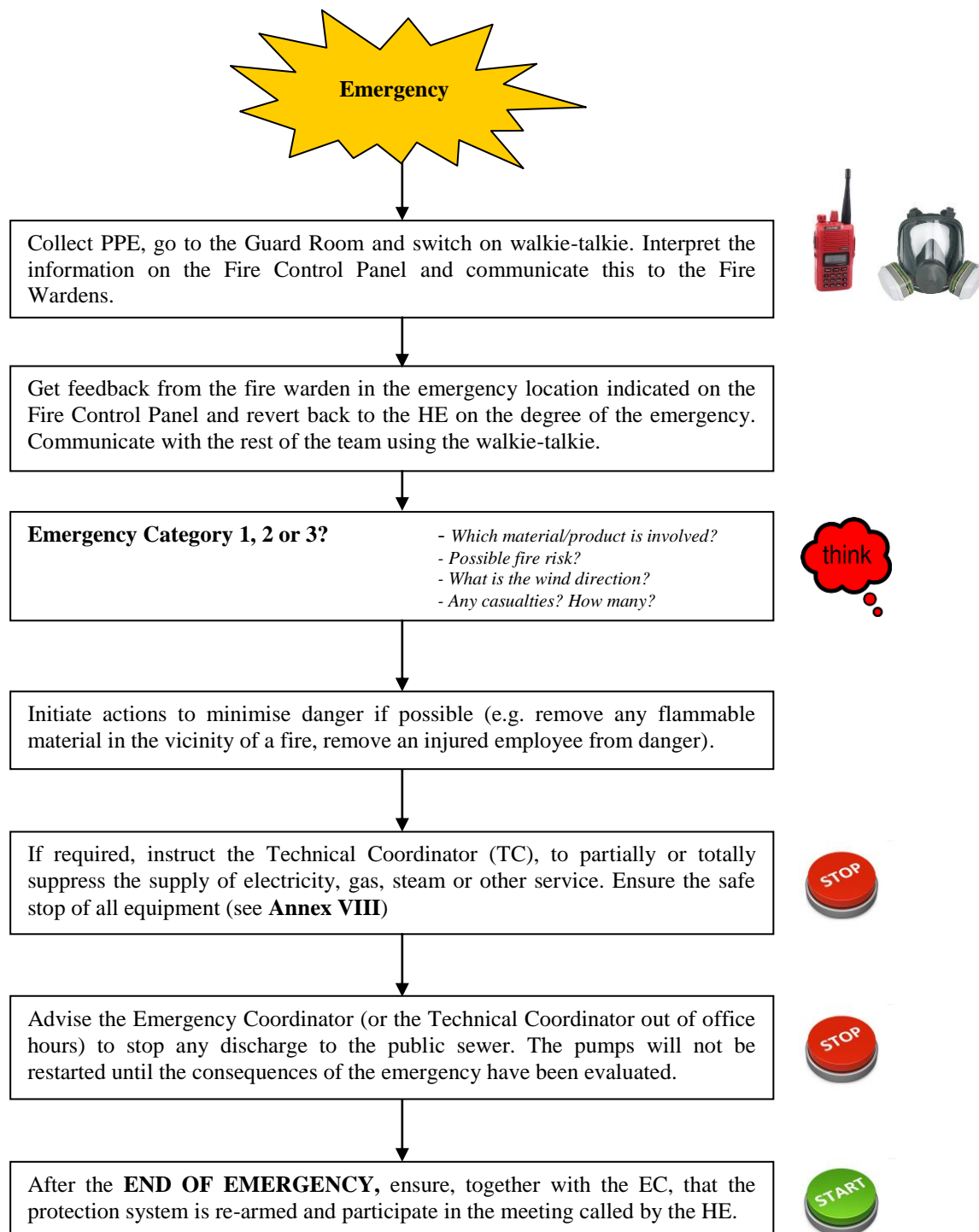
4.1.3 Procedure for the Security Guard (SG)



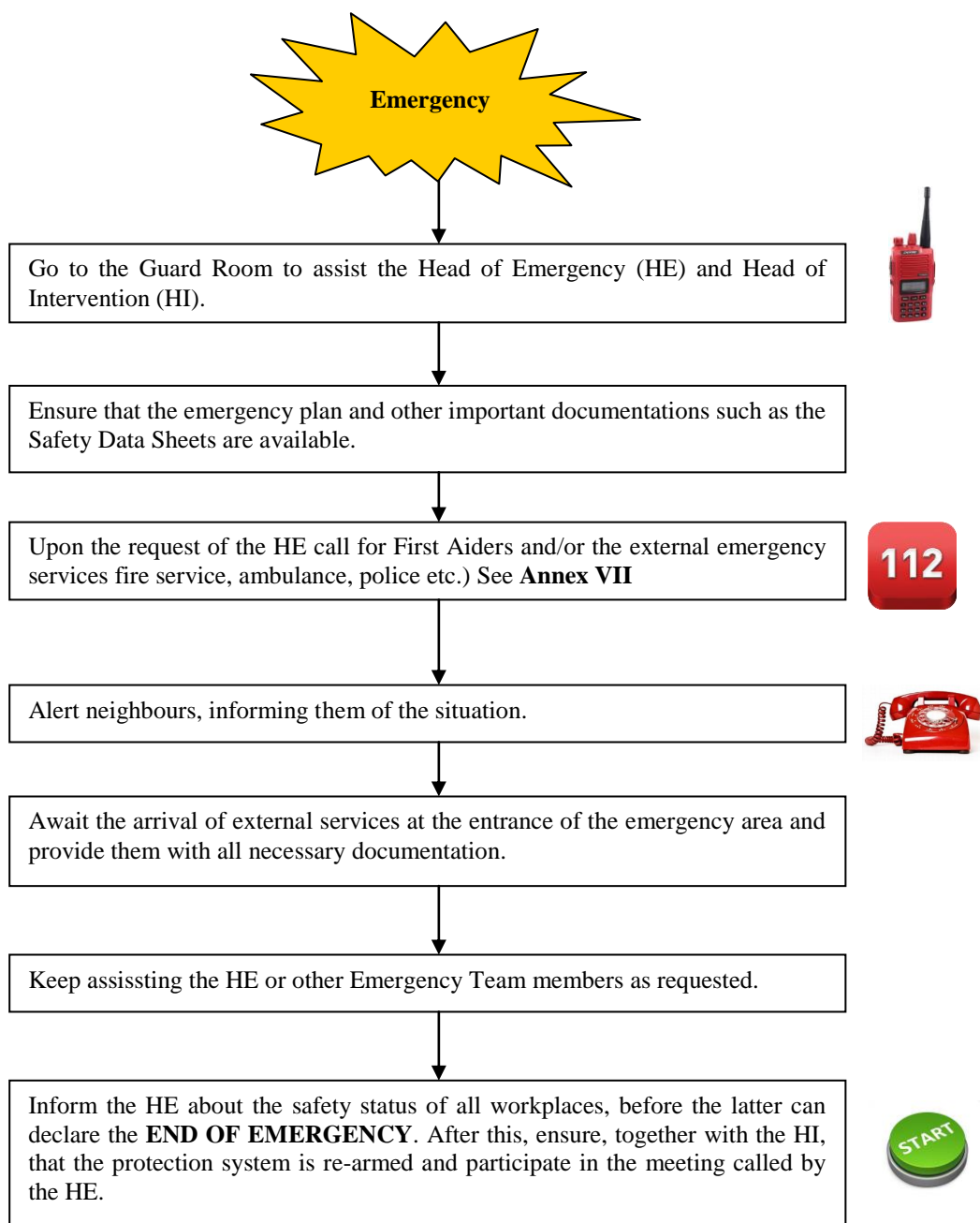
4.1.4 Procedure for the Head of Emergency (HE)



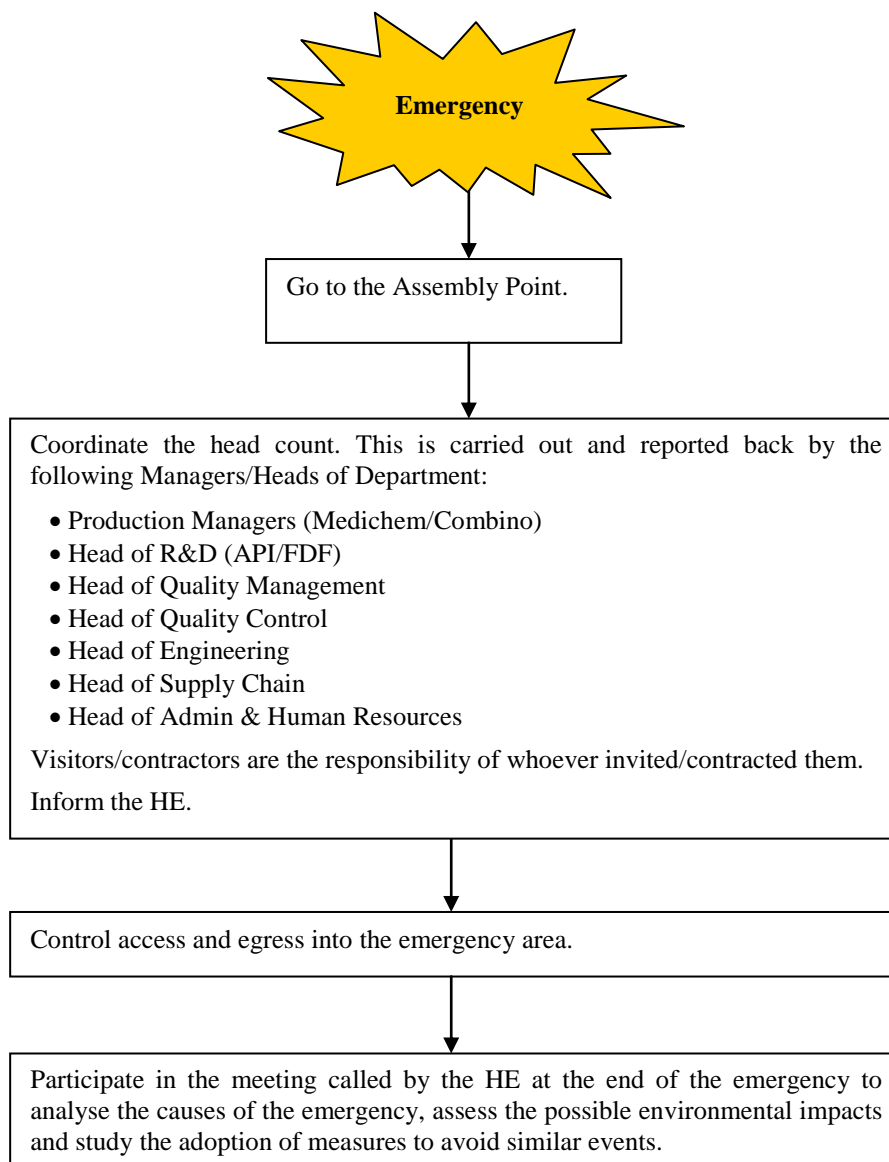
4.1.5 Procedure for the Head of Intervention (HI)



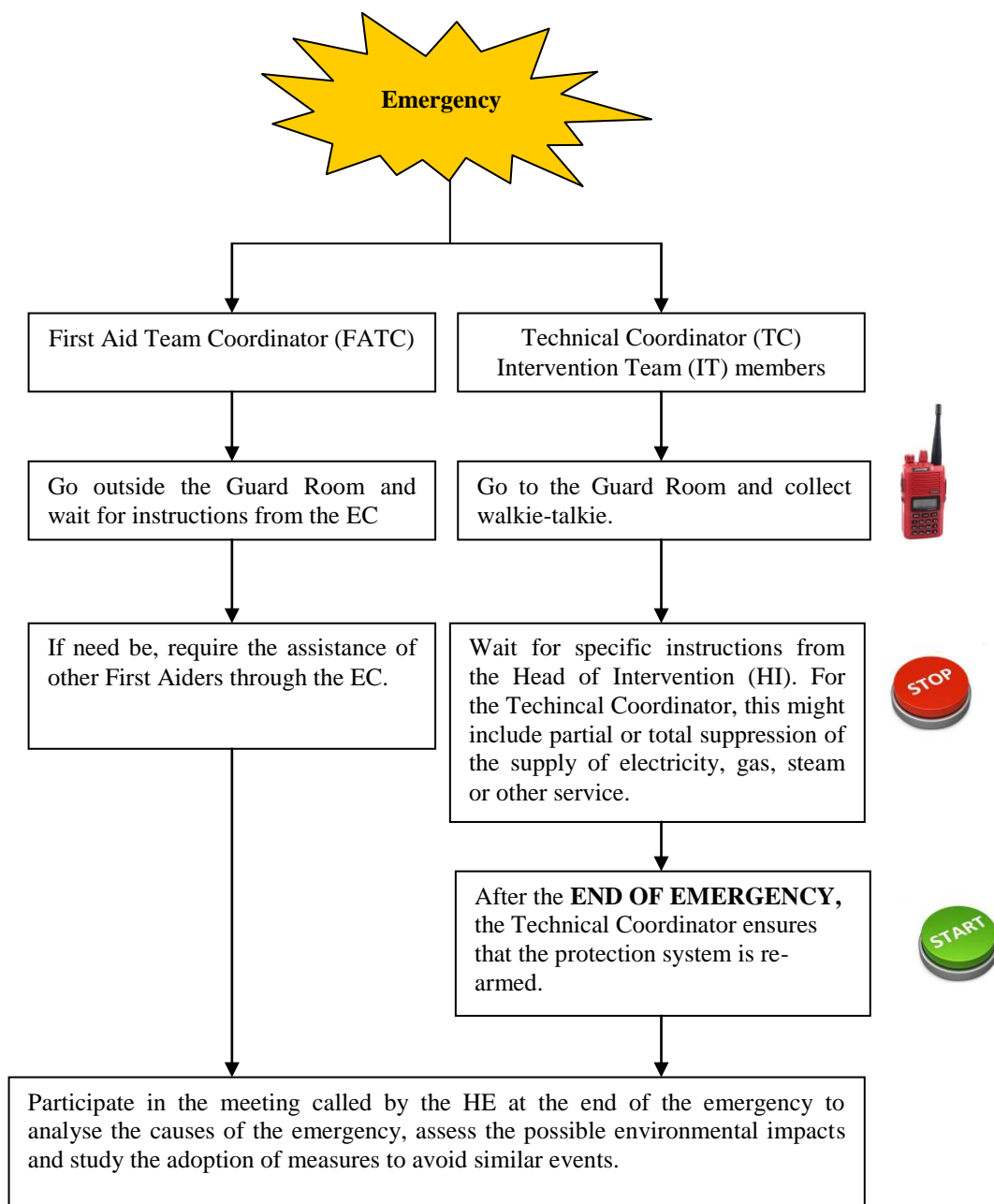
4.1.6 Procedure for the Emergency Coordinator (EC)



4.1.7 Procedure for the Cordon Officer (CO)



4.1.8 Procedure for the First Aid and Intervention Teams (FATC, FAT, TC, IT)



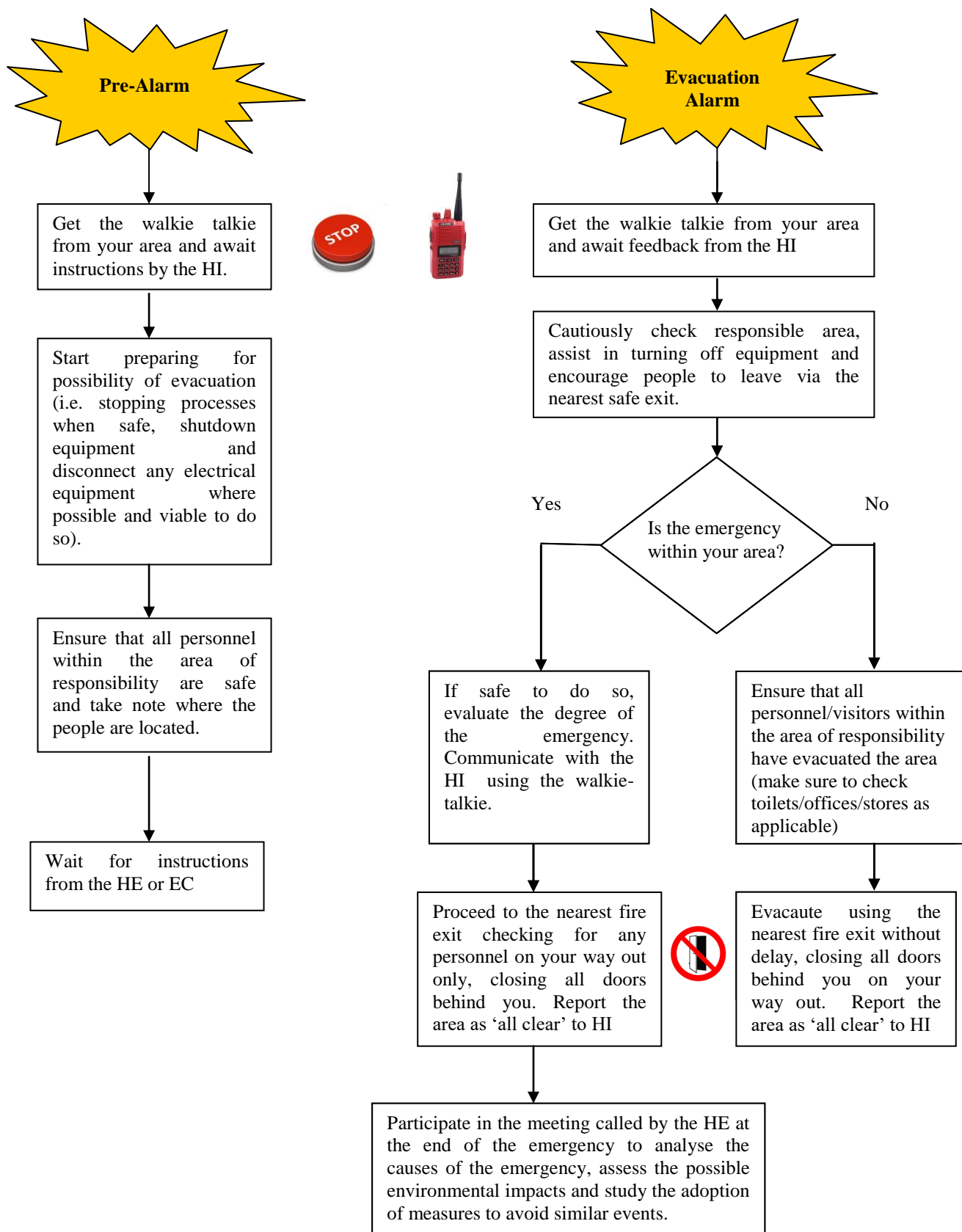
At the end of the emergency, it will be necessary to collect any spilled material and advise the EPHS Manager so that appropriate disposal can be arranged. **Annex IX** outlines the procedures to be followed while ensuring proper environmental practices.

4.1.9 Procedure for the Fire Warden

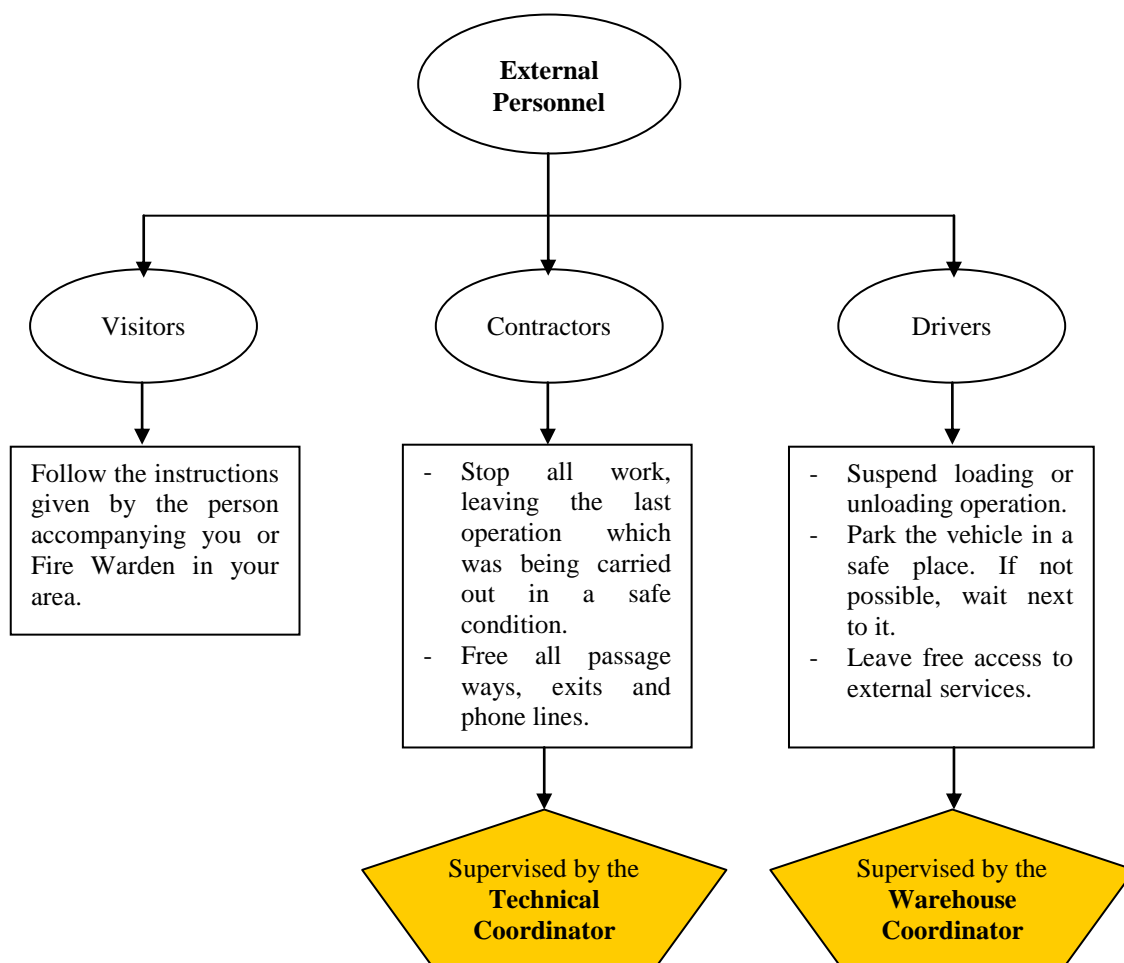
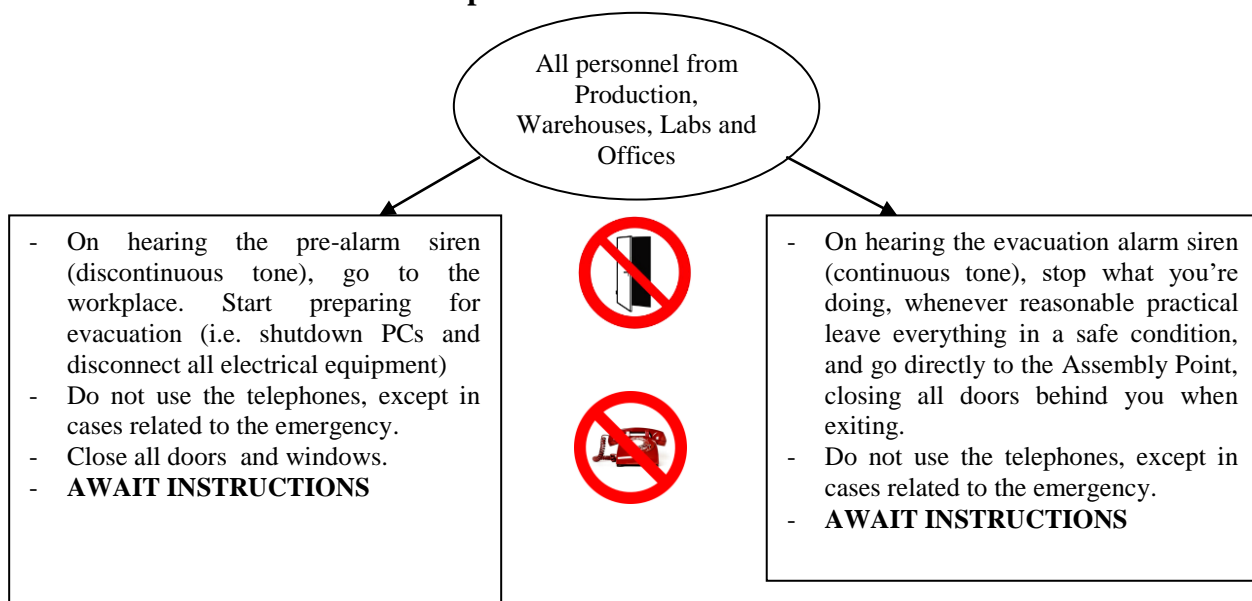
The following are the areas where Fire Wardens are assigned to:

- API Production Area – Internal warehouse
- Medichem Administration Area & R&D
- FDF Production Area
- FDF Warehouse Area
- QC Laboratories Area

The following is the procedure to be followed by Fire Wardens:



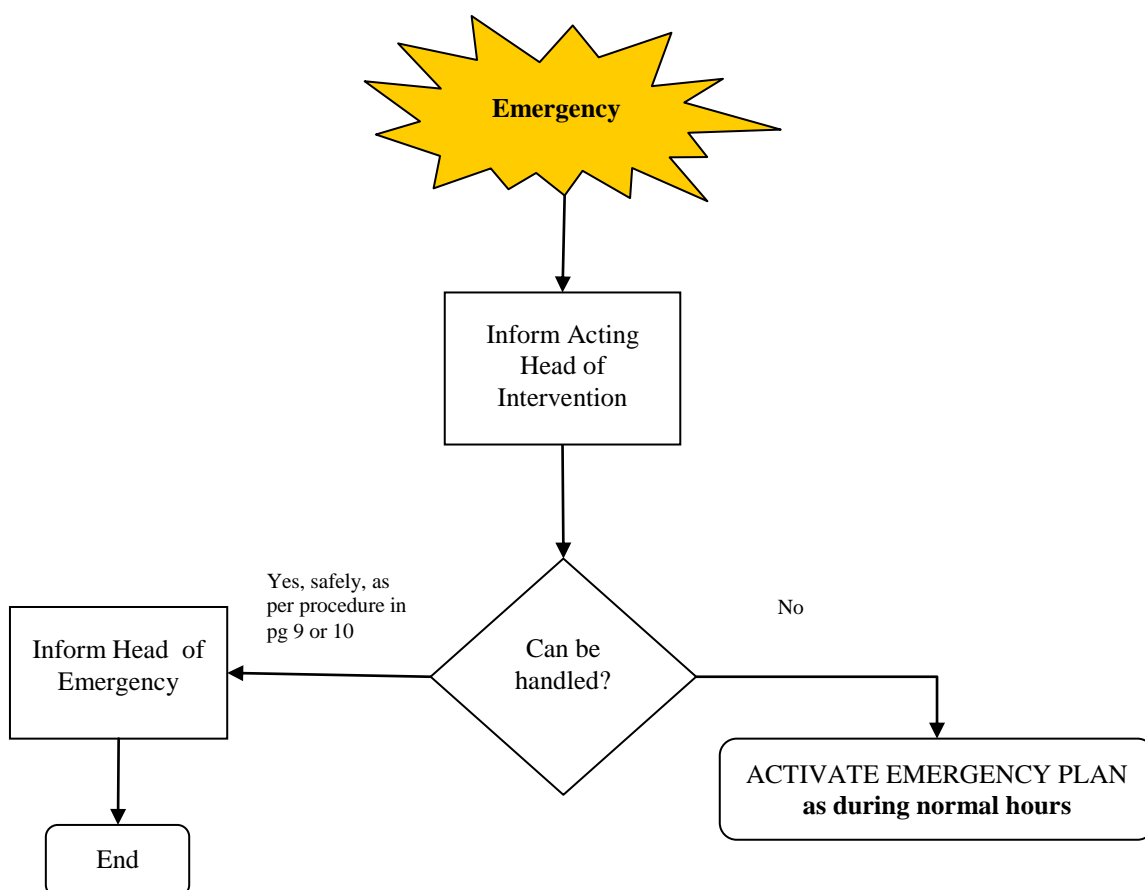
4.1.10 Procedure for all other personnel



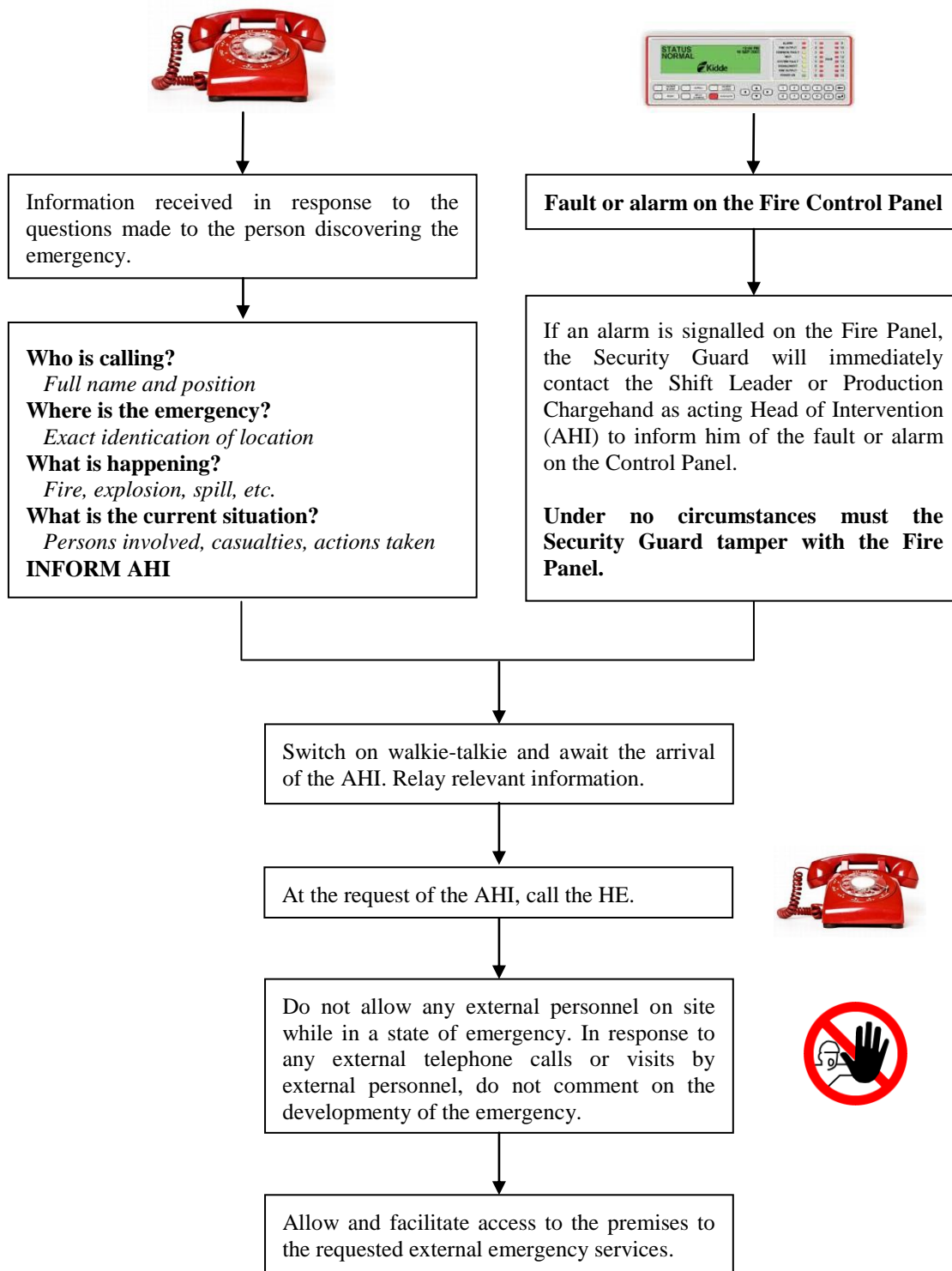
4.2 Actions outside normal hours (Mon – Fri 17:00 – 08:00 and Production Weekends)

In the case of emergency situation outside office hours, the Shift Leader (Medichem) or Production Chargehand (Combino) is the person of highest responsibility and will act as the Acting Head of Intervention (AHI). The Shift Leader or Production Chargehand has to locate the employees on site to ensure that they are in a safe area. As soon as the emergency situation is confirmed, the Shift Leader or Production Chargehand will instruct the Security Guard to call the Head of Emergency (who may then request the support of the Head of Intervention and/or Emergency Coordinator). The Shift Leader or Production Chargehand may also request the help of external emergency services if required. Upon the arrival of the HE, HI or EC the Shift Leader or Production Chargehand will undertake tasks as instructed.

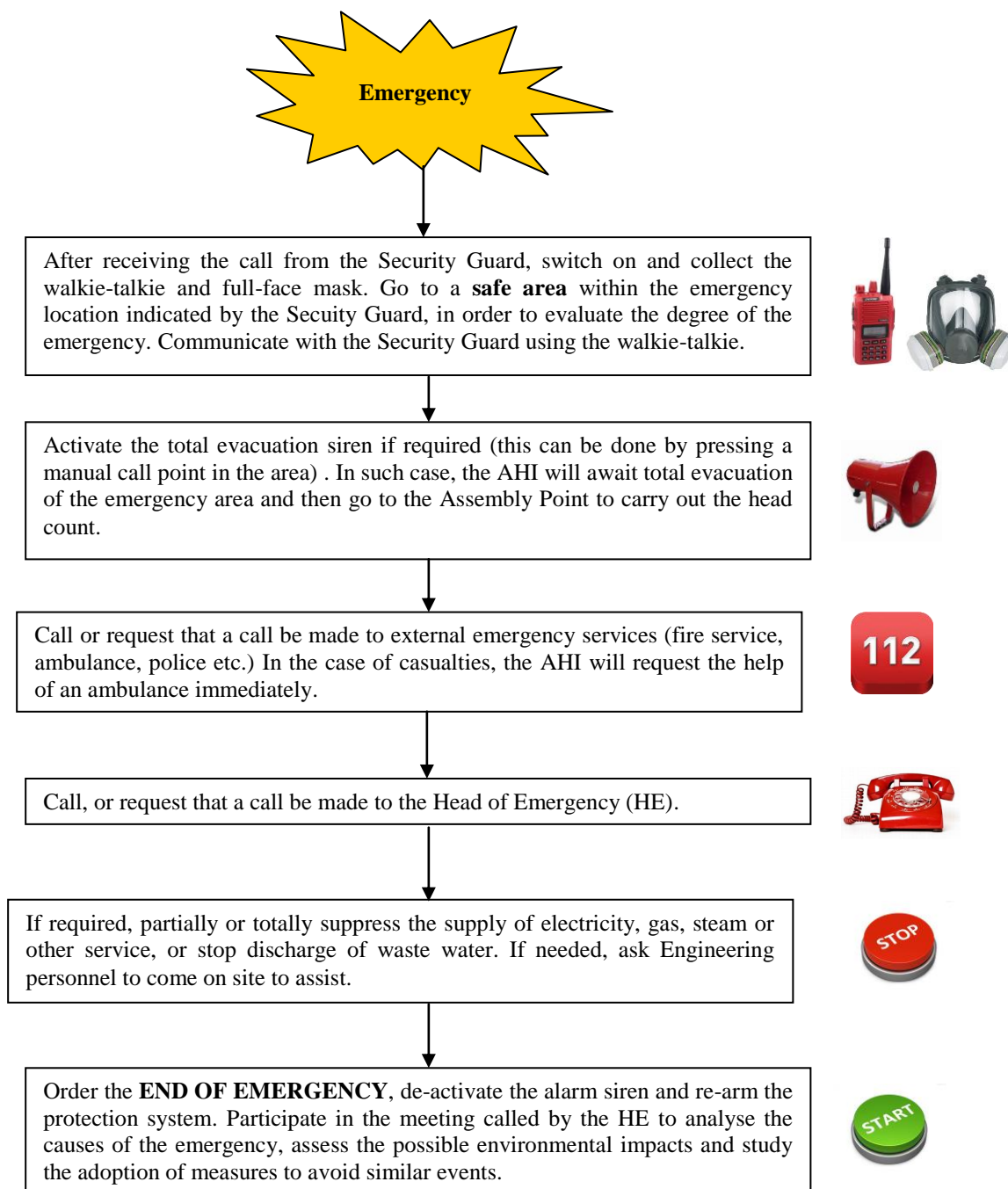
4.2.1 Procedure for the person discovering the emergency



4.2.2 Procedure for the Security Guard (SG)



4.2.3 Procedure for the Acting Head of Intervention (AHI)



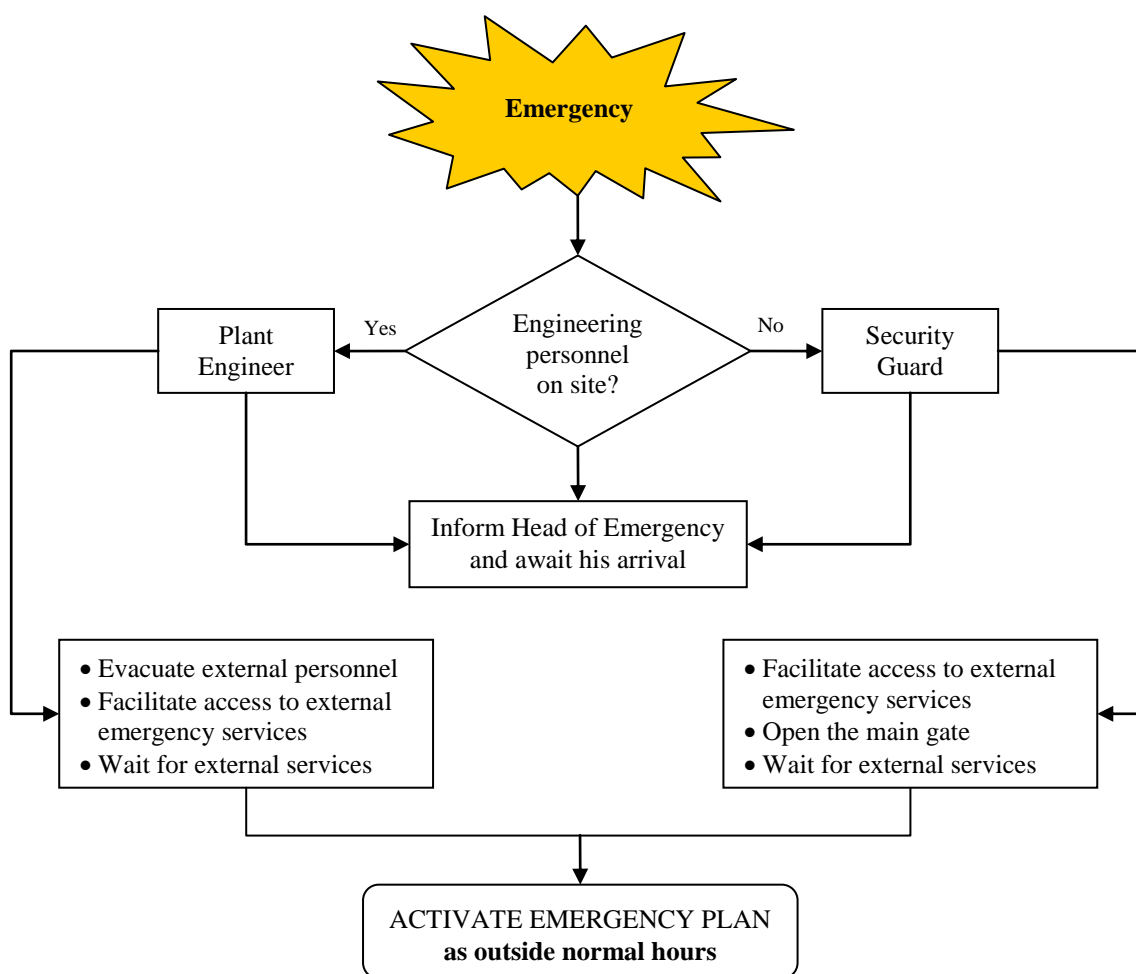
4.3 Actions during weekends and shutdowns (with Engineering personnel on site)

In the case of an emergency situation during weekends and shutdowns, the Engineer/Technician on site will be the person of highest authority and will act as Acting Head of Intervention (AHI). He/she has to locate all employees and external personnel on site (e.g. contractors) to ensure that they are in a safe area. As soon as the emergency situation is confirmed, the Engineer/Technician on site will instruct the Security Guard to call the Head of Emergency (who may then request the support of the Head of Intervention and/or Emergency Coordinator). The Engineer/ Technician on site may also request the help of external emergency services if required. Upon the arrival of the HE, HI or EC he/she will undertake tasks as instructed.

4.4 Actions during weekends and shutdowns (without Engineering personnel on site)

In the case of an emergency situation during weekends and shutdowns, the Security Guard will call the Head of Emergency (HE) on the emergency mobile number shown on **Annex II**.

The HE will then decide on the actions to be taken.



4.5 Actions for lone workers, especially during out of office hours or shutdowns

In the case of a person needing to work alone, unattended (e.g. maintenance work, work in the R&D Laboratory, QC analysis), in particular out of office hours or during shutdowns, the person will need to take a walkie-talkie from the Guard Room and advise the Security Guard about the location where the work will be carried out. The walkie-talkie will need to be carried on the person at all times. In the case of an accident, if the person falls unconscious, the man-down function will be triggered after 10 seconds. There is also a Lone Worker function (see **Annex X**).

The Security Guard is to try and contact the person via walkie-talkie. If not, he/she will try to physically locate the person within the location indicated by the worker upon entering the site. If the person is not located contact the Head of Emergency and await instructions. If the person is found injured or unconscious call immediately the external emergency services, followed by the Head of Emergency. Do not move person.

5. Telephoned bomb threat or suspect package

5.1 Telephoned Bomb Threat

Any person that receives a bomb threat by telephone should try to obtain as much information as possible from the caller in the shortest possible time. Thereafter, the HE (or the next person in the Chain of Command on page 5) is to be informed, and will follow the procedure below.

Call 112, asking for the Control Room of the Armed Forces of Malta or the Bomb Disposal Unit, giving the following information:

- Your full name and position
- The position of your site (Medichem Manufacturing Malta Ltd. or Combino Pharm Malta Ltd.)
- Your telephone number

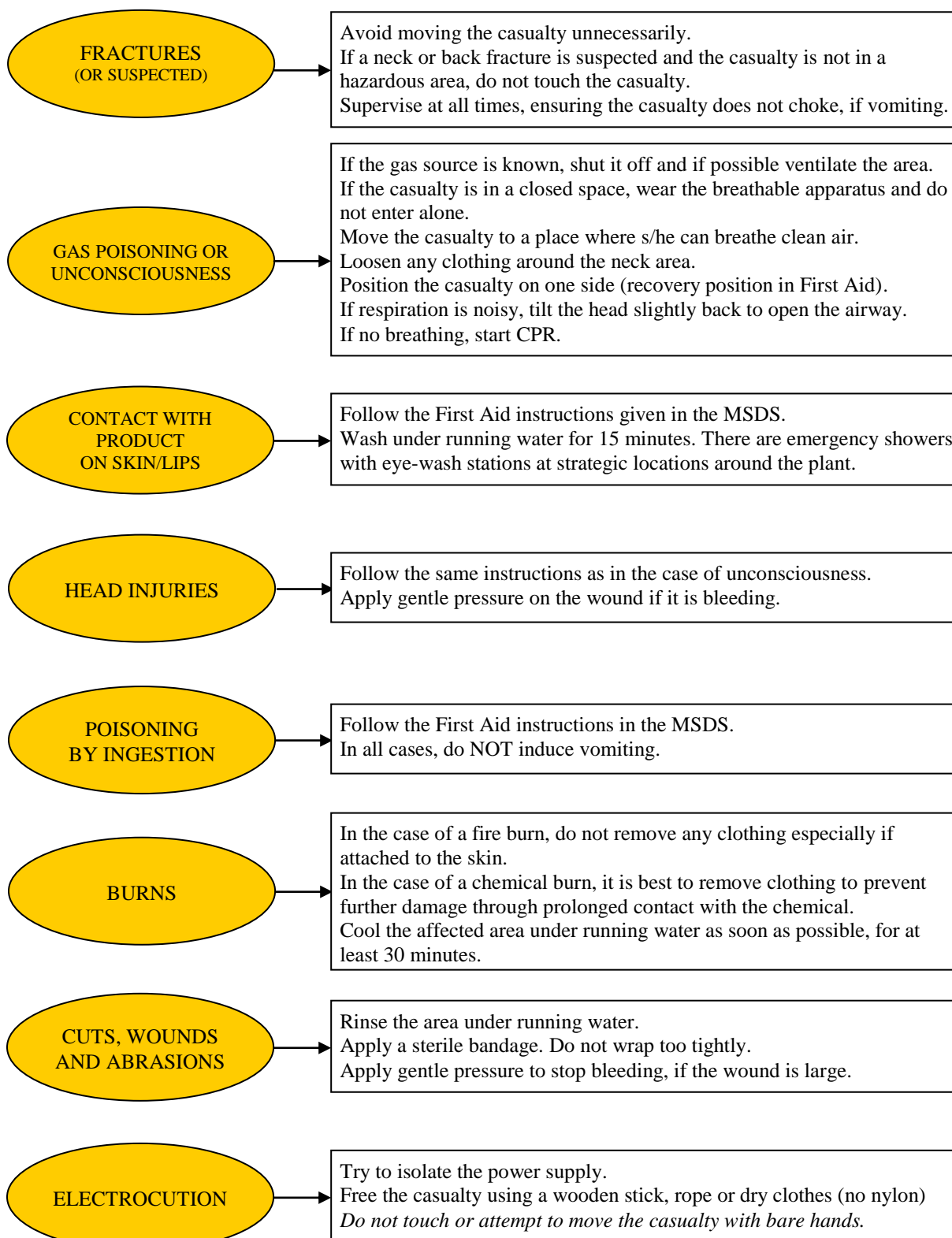
No persons shall be allowed to enter the premises until the area is declared safe. All employees on site should be evacuated to the Assembly Point in a coordinated manner keeping the process under control. Everyone should await the arrival of the external personnel, who will take charge of all necessary procedures.

5.2 Suspect Package

Should anyone discover a suspect package, he/she should:

- **UNDER NO CIRCUMSTANCES TOUCH OR MOVE THE PACKAGE.**
- Warn all persons in the vicinity to keep clear.
- Inform the HE (or the next person in the Chain of Command on page 5) who will follow the same procedure as in the case of a bomb threat.

6. Actions to be taken in cases of personal injury



7. End of the Emergency

As soon as the emergency situation is cleared, the Head of Malta Operations (or the EPHS Manager in his absence) must inform the company COO.

A meeting will then be held between the HE, HI, HC, EC and Fire Wardens to analyse the emergency situation. The following points will be evaluated in the meeting:

- **The causes of the incident:** The facts which arose during the emergency situation.
- **Actions carried out during the emergency:** This is to evaluate what can be improved to achieve greater effectiveness in future emergency procedures. In this way, the effectiveness of the current Emergency Plan and possible improvements will be evaluated.
- **The possible environmental impact on the different environmental sectors:** Taking into special account possible effects on waste water (sewage) and atmospheric emissions.

The objective of this evaluation is to establish appropriate procedures so that the incident does not re-occur, to improve emergency action and minimise the environmental effects of such incidents.

8. Reporting after the Emergency

The conclusions of meeting described in Section 7 will form the body of an internal report, circulated to the COO, HE, HI, HC and EC.

Additionally, the following external reports may need to be drawn up:

- 1) In the case of casualties, report to the Occupational Health & Safety Authority, as required by local legislation (Legal Notice 52 of 1986, as amended by Legal Notices 22 and 71 of 1996, Act XXVII of 2000, Legal Notice 44 of 2002 and Legal Notices 35, 36 and 121 of 2003), within 7 days from the date of the accident.
- 2) In the case of environmental incidents, notification to the Environment and Resources Authority as part of the obligations of the IPPC Permit (currently Conditions 5.1 and 5.2 and Schedule 1 of IPPC permit IP 0002/05).
- 3) In the case of transport (ADR) related accidents, notification to the Road Transport Licensing Unit at Sa Maison Road, Floriana FRN1612, within 7 days from the days of the incident.
- 4) Similar reports or press releases may be required by the Birżebbuġa Local Council, immediate neighbours, other stakeholders and the general public through local media.

9. ANNEXES

This revision of the Emergency Plan contains the following Annexes:

Annex I	Street Map of Hal Far
Annex II	Useful Contact Numbers
Annex III	Emergency Flow Diagram
Annex IV	Emergency Team
Annex V	Emergency exits and recommended escape routes <u>Medichem</u> <ul style="list-style-type: none">- External Evacuation Routes- Office and Laboratory Block- Internal Warehouse- Utility Areas- First Floor Manufacturing Area- Second Floor Manufacturing Area- Physical Treatment (Clean) Area- HPAPI Unit <u>Combino</u> <ul style="list-style-type: none">- Ground Floor Evacuation Routes- First Floor Evacuation Routes
Annex VI	Legend of Evacuation Signs
Annex VII	Models for external communication
Annex VIII	Safe Stop and Start
Annex IX	Safe collection of Spillages
Annex X	Entel [®] HT-985 Walkie-talkie
Annex XI	Environmental Aspects in emergency situations (applies to Medichem only)
Annex XII	Explosive Atmosphere Zones
Annex XIII	Plans indicating hazardous goods storage areas
Annex XIV	Important Contacts List