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Introduction

This document has been written to amplify the recommendations given in WHO Technical Report Series No. 961, 2011: Model guidance for the storage and transport of **Time- and Temperature-Sensitive Pharmaceutical Products**. (TTSP)

Requirements

Ensure that buildings used to store TTSPs have sufficient security to prevent unauthorized access and to prevent misappropriation of goods.

Ensure that all areas that are used to store controlled or hazardous TTSPs are:

- Dedicated, securely locked facilities that fully comply with all legislative and regulatory requirements applicable in the country where the store is located;
- Only accessible to authorized staff;
- Protected by automatic intruder and/or fire and smoke, and/or chemical and/or radiological sensor alarm systems appropriate to the type(s) of product being stored;
- Designed to be explosion-proof, where explosive TTSPs are stored; and
- Continuously monitored by security staff or by a qualified external security company. Continuous monitoring may be on-site or remote.

Provide suitable fire detection and fire-fighting equipment, including fire hydrants, in all TTSP storage areas and ensure that:

- Systems and equipment are appropriate for the class of occupancy and product storage arrangements and are approved by the local fire authority, and

- b. Equipment is regularly serviced in accordance with the equipment manufacturers' recommendations and local regulations.

Follow standard operating procedures (SOPs) for fire prevention, detection and control and **train staff and carry out regular fire drills**. Prohibit smoking in all areas.

Objectives

The objectives of this document is to provide guidance on how to meet the above requirements with regard to building security, fire prevention, fire detection and management of the buildings.

Target Audience

This document is written for managers of the buildings used to store TTSPPs, security personnel and the person designated as the "Responsible Person" who must carry out a fire risk assessment of the premises.

Guidance

An effective health service is dependent upon an assured supply of drugs; many of these products have a street value if they are misappropriated. It is essential that compounds containing buildings used to store TTSPPs in significant quantities should be adequately protected against fire and theft.

Site Security and Emergency Access

Compounds containing pharmaceutical stores should be surrounded by perimeter fencing or walls of a suitable height to ensure the security of the grounds and storage buildings against vandalism, theft or arson. If local codes do not permit perimeter fencing, alternative measures to provide perimeter protection should be provided. There should also be a security gatehouse to monitor vehicles entering and leaving the site. If resources permit, there should be perimeter lighting and monitoring by closed-circuit television (CCTV). This is the first level of protection needed to prevent unauthorized access and to prevent theft. Additional levels of security are needed within the individual buildings on the site.

Access roads should be provided to all buildings on the site so that vehicles can deliver goods to the storage facility. Building Regulations also require adequate access to a minimum

percentage of the building perimeter so that fire and rescue service vehicles can reach the source of a fire; this percentage increases with the aggregate area of the individual building.

General Building Security

Windows and doors at ground floor level are most vulnerable and therefore they should be fitted with good quality locks. Shutters or fixed security bars are also recommended on windows. Preferably buildings should be protected by an automatic intruder alarm system.

The building should be kept locked and all keys should be kept under close control. Keys should be distributed to nominated key holders only and regular checks should be made to ensure that they have not been lost. The locks should be of a type whose keys cannot easily be copied, or can only be duplicated with the written authorization of the building manager.

If resources permit, key fob and/or number code entry systems should be used instead of keys. This type of entry system eliminates the need for additional keys to be cut and allows access to be recorded on a computer. This technology also allows lost key fobs to be deleted easily from the system and door codes to be changed regularly.

Where resources permit an audio or video entry system is recommended for additional security.

Controlled and Hazardous Substances Areas

All areas used to store controlled or hazardous TTSPPs must be securely locked and must fully comply with all legislative and regulatory requirements applicable in the country where the store is located.

These areas should only be accessible to authorized staff and protected by a suitable range of automatic alarm systems appropriate to the types of products being stored and the likely risks. These alarm systems may include intruder detection, fire and smoke, and sensor systems to detect chemical and/or radiological hazards. Areas used to store potentially explosive substances should be designed to be explosion-proof. All areas should be continuously monitored by security staff by carrying regular patrols, as a minimum, or by closed-circuit television (CCTV) where resources permit.

Fire Detection Systems

Suitable fire protection equipment should be provided in all TTSP storage areas. It is essential that the following are provided:

Automatic Fire Detection and Alarm System This should be designed, installed and maintained to the relevant standards.

First Aid Fire Fighting Equipment: This should include hand held fire extinguishers selected and maintained to the relevant standards.

In order to meet the requirements of local Building Regulations a manual alarm system may be the minimum standard required in warehouses since there is no sleeping risk. However there are often circumstances where an automatic fire detection system is needed. This could be needed to compensate for some departure from the guidance in the local building code, or as a component of the operating system for a fire protection system. It may also be needed where a fire could break out in an unoccupied part of the building which prejudices the means of escape from the occupied parts.

Automatic detection should be designed, installed and maintained in accordance with the relevant standard⁶. If maintenance of fire detection and firefighting systems and equipment is contracted out, this should be under the terms of a clearly defined Service Level Agreement (SLA).

Fire Suppression Equipment

The following protection systems are desirable where resources allow:

An Automatic Sprinkler System(fire suppression system): This should be designed, installed and maintained to the relevant standard;

A Smoke Ventilation System This may be automatic or manually operated.

Sprinkler Systems

An automatic fire suppression system should be provided in accordance with the relevant standards⁷. It is recommended that the system should be installed and maintained by a contractor who carries appropriate third party accreditation.

Fire-fighting water can be supplied from one of the following sources:

City Mains Water Supply: The agreement of the water authority is usually required for a city mains connection. Where water quality is poor, strainers must be fitted on all connections to the mains supply.

Storage Tanks: This can be a pump suction tank, gravity tank or reservoir.

Inexhaustible Sources: This includes lakes or rivers.

Pressure Tanks.

Wet pipe sprinklers should be used in high bay warehouses – this means that the sprinkler network is fully charged with water at all times. The use of the alternative dry pipe system could result in an unacceptable time delay between the activation of a bulb and the flow of water through the sprinkler head.

Where the goods are stored in pallet racks the provision of in-rack sprinklers as well as roof level sprinklers is recommended. The sprinkler bulbs in the in-rack sprinkler heads activate at a much lower temperature than those at roof level; consequently the fire-fighting water is discharged in a more localized area. This means that the fire can be contained with a lower amount of water damage than would be expected from the discharge of roof level sprinklers.

In cold climates, the installation may require protection against freezing if the pipe work passes through unheated spaces. Freeze-protection can be achieved using anti-freeze liquid or electrical trace heating. Where sprinklers are installed in cold rooms or freezer rooms, dry pendant drops should be used. With this arrangement, sections of dry pipe serve the relevant risk area and the actual flow valves are located outside the cold store. This prevents the water in the system from freezing.

Smoke Ventilation Systems

Automatic smoke vents are generally provided to assist means of escape from the building. By venting smoke build-up at high level, the occupants can escape from the building underneath the smoke layer in reasonably safe conditions. Additional manually operated smoke vents are generally provided to aid the fire and rescue service with smoke clearance once the fire has been extinguished.

Where both sprinkler systems and smoke vents are provided in a building the interaction between them must be carefully considered. Research by Factory Mutual in the early 1970s, which remains relevant, showed that the provision of automatically operating smoke vents can cause delays in the operation of sprinkler system. The reason for this is that automatic smoke vents open when triggered by smoke, whereas sprinklers operate when heat is detected. As smoke is generally detected more quickly than heat, Factory Mutual concluded that sprinklers would perform more effectively if there were no vents. Their reasoning was that the building would fill with smoke; this creates low

oxygen conditions which limits combustion, allowing the sprinklers to extinguish the fire more effectively.

However, where life safety is the predominant requirement and a smoke control solution is used to protect the escape routes within a building, current guidance requires the smoke vents to operate automatically; the vents will therefore activate before the sprinkler system.

Alternatively, if the fire service response time is short, and the sprinkler system is provided with fast response heads, the smoke ventilation system may be activated by the flow switch in the sprinkler supply.

Compartmentation

Buildings are often divided into compartments enclosed in fire-resisting construction; this approach provides passive fire protection by inhibiting the spread of fire within the building. In order to comply with local Building Regulations, the size of individual compartments may have to be limited. Compartment size is determined by the overall size of the building, the number of stories, and whether or not an automatic sprinkler system is provided.

Fire prevention, training and control procedures Preventing fires from occurring. Fire safety systems to deal with a fire incident. The main objective is to create an operating environment in which fires are prevented from starting in the first place. If a fire does break out, the aim is to prevent it from developing beyond a very minor event.

Risk Assessment

The first step in fire prevention is to assess the risks and record them in a risk register⁸. Review and assess the means by which a fire might start and spread, the potential consequences and the available approaches to risk mitigation. This includes day-to-day operations, risks associated with periodic building and maintenance work and those arising from installing new equipment, or adopting new or changing technologies.

Fire Prevention

Set out below are the principal actions that need to be taken to monitor the behavior of workers and prevent fires from occurring.

- Smoking is one of the greatest fire risks and it should be prohibited in all buildings and workplaces. Where there is no legal prohibition, smoking should only be allowed in designated smoking areas and fire-safe ashtrays and bins should be provided.
- Enforce good housekeeping practices; this includes implementing routines for the regular removal and disposal of waste;
- Establish and maintain out-of-hours inspection and security procedures, including means of preventing arson;
- Carry out routine checks, inspections, and tests, including monitoring the maintenance of heat generating equipment that could cause fires, chafing of cables, self-heating of cables due to electrical resistance and checks on fuel supplies and storage.
- Issue and control work permits and associated procedures;
- Instruct and supervise contractors and sub-contractors carrying out construction and maintenance operations within the building;
- Avoid conditions leading to gas and dust explosion hazards;
- Maintain integration with other systems (e.g. ventilation, communications).

Fire Safety Training

All employees should be given fire safety training by a person who is competent in the subject and who understands effective training methods. If relevant expertise is not available within the organization, an independent expert – for example from the fire brigade – should be engaged to provide training.

Fire safety training should start with induction training on the first day of appointment of new staff. There should be refresher training at least once a year to ensure that all staff are familiar with the fire precautions for the workplace and are reminded of the actions to take in an emergency. More frequent training should be given where there is a high turnover of staff, or a high risk of fire.

All staff, including part-time staff, security staff, cleaning staff and contractors should be trained and instructed in Risk awareness;

- Smoking policy;

- Basic fire prevention;
- Good housekeeping;
- The fire routine:
 - Actions to be taken when a fire is discovered or an alarm is heard;
 - Knowledge of the escape routes and exits, especially those not in regular use;
 - Raising the alarm and the location of alarm indicator panels;
 - Arrangements for calling the fire and rescue service;
 - Special provisions for assisting disabled people;
 - Location of fire-fighting equipment;
 - Selection and use of fire-fighting equipment, including hand held fire-fighting equipment (in larger premises it may be appropriate to train specific staff instead of all staff);
 - The importance of fire doors and the need to close all doors at the time of a fire and/or on hearing the fire alarm;
 - Process shut down and shutting down of non-essential equipment, stopping machines and processes and isolating power supplies if appropriate;
- Evacuation procedures.
- Incident reporting procedures, including for “near miss” events and false alarms. “No blame” reporting culture should be encouraged

Supervisory and other staff who have specific responsibility for fire safety should receive detailed instruction in their own duties and appropriate refresher training at least once, and preferably twice a year. Staff with particular responsibilities are likely to include:

Department heads;

- Fire marshals or fire wardens; x Floor supervisors;
- Security staff (including night security patrols);

- Engineering and maintenance staff;
- Receptionists and telephone operators.

Fire Control Procedures

Follow the standard operating procedure (SOP) for housekeeping
Follow the standard operating procedure (SOP) for routine inspection of fire safety installations.

Fire Safety Housekeeping

In order to protect property and life, standard operating policies should be followed for fire prevention, detection and control.

This SOP describes the housekeeping routines that should be followed in order to manage fire safety and to prevent fires from occurring within the building

Responsibility

The Fire Safety Manager or Environmental Health and Safety (EHS) Manager has day-to-day responsibility for the prevention of fires.

Procedure

Reducing ignition sources

Identify and control potential ignition sources.

Responsibility

Fire Safety or EHS Manager

- a. Smoking Smoking is not permitted in any areas of the building. Control illicit smoking by appropriate management, or consider providing smoking areas outside the building provided with fire safe ash-trays and bins.
- b. Naked flames, e.g. candles, or heaters using naked flames are not permitted
- c. Hot works⁹ will only be carried out after a permit to work has been issued
- d. Food and drink preparation and consumption will only be carried out in rest areas designated for this purpose.
- e. Misused or faulty electrical equipment should be reported immediately and replaced or removed

- f. Overheated or worn cables should be repaired or replaced
- g. Lighting displays, e.g. halogen lights, should not be placed near flammable material.
- h. In areas where flammable, volatile or explosive materials are stored, ensure that electrical fittings are suitable for the risk classification.
- i. All equipment should be installed, maintained, used and managed in the appropriate manner by competent persons. This should be supported by staff training

Reducing Fuel Load

The amount of combustible material should be reduced, or stored more safely.

Responsibility.

Fire Safety or EHS Manager

- a. Reduce the fire load. For example replace bottled gas heating with electric heating sources, or reduce the amount of bottled gas stored within the building
- b. Store goods in an appropriate manner, e.g. in dedicated store rooms.
- c. Store and use highly flammable substances safely, and store in appropriate storage containers.
- d. Control the amount of rubbish and how it is stored. Store rubbish in a safe location away from buildings, preferably in a designated area. Rubbish bins within the building should be emptied on a daily basis.
- e. Remove redundant services from voids as these can constitute a significant fire load

Maintenance of fire protection measures

Check regularly that fire protection measures are available at all times and able to carry out their function in a fire.

Responsibility.

Fire Safety or EHS Manager

- a. Keep escape routes clear at all times. Goods and equipment must not be stored on escape routes or allowed to block exits, as this provides an unwanted fire load and a potential ignition source and constitutes a life safety risk
- b. Maintain door locks, panic bars and automatic door release mechanisms so that they open easily in an emergency.
- c. Do not obstruct fire alarm call points, portable fire extinguishers or fire hydrants with stored goods, machinery or parked vehicles.
- d. Maintain and test all fire safety equipment (fire alarms, emergency lighting and fire extinguishers) in accordance with the relevant standard by competent persons – see companion SOP: Routine inspection and maintenance of fire safety installations.
- e. Certain parts of the building may contain flammable elements which can contribute to fire spread, such as insulated core panels surrounding cold rooms and other temperature controlled areas. Panels should be checked regularly and any damaged panels repaired
- f. Goods should not be stored close to windows. If the building has a sprinkler system goods should not be stacked higher than the maximum height recommended in the applicable standard

Routine Inspection and Maintenance

In order to protect property and life, standard operating policies should be followed for fire prevention, detection and control.

Objectives

This SOP describes the routine inspections that should be carried out on any fire safety installations provided in the building

The fire safety equipment provided within the building including passive fire protection provisions, should be inspected frequently. Most of the inspection can be undertaken by suitably trained personnel; however if installations such as automatic sprinkler systems and smoke ventilation systems are provided then a formal Service Level Agreement (SLA) should be made with the installer

to provide regular inspection and testing in accordance with the applicable standards.

Responsibility

The Fire Safety or Environmental Health and Safety (EHS) Manager has day-to-day responsibility for the prevention of fires.

Note: It is essential to designate a Fire Safety Manager or Environmental Health and Safety (EHS) Manager to oversee the activities described in this SOP.

Associated Materials and Equipment

- a. Check automatic fire detection alarm systems to ensure that:
- b. Every lamp is lit, if it is a maintained system
- c. The control panel for any central battery system or generator indicates normal operation;
- d. Check sprinkler system to ensure that:
 - There is continuity of the connections between the alarm switch and the control unit and between the control unit and the fire and rescue service;
 - The water level and air pressure are correct in any pressure tank that provides a duplicate supply;
 - Any corrective actions are taken
- e. Fire doors that are held open by automatic release mechanisms should be released daily.
- f. Check every point where a portable fire extinguisher or hose reel is usually located. Missing or damaged fire extinguishers or hose reels should be replaced or repaired immediately. Any extinguishers used in a fire, or for training or which are otherwise discharged, should be recharged immediately.
- g. Document findings and corrective/preventive actions if applicable.

Weekly Inspections

Responsibility

Fire Safety or EHS Manager.

- a. Check automatic fire detection and alarm systems to ensure that:
 - The control equipment is able to receive a fire signal and to initiate the

evacuation procedure, recording which trigger device has been used;

- Any standby batteries are in good condition and the fuel, oil and coolant levels of any standby generators are correct and topped up if necessary.

b. Check the sprinkler system to ensure that:

- Water and air pressure gauge readings on installations, trunk mains and pressure tanks, and water levels in elevated private reservoirs, rivers, canals, lakes, water storage tanks, etc., meet the design criteria and that all gauge readings and levels are recorded;
- Each water motor alarm has been sounded for at least 30 seconds;
- Automatic pumps start when the water pressure reaches low level;

For Automated Pumps Powered By A Diesel Engine:

The fuel and oil levels of the engine meet the design and/or manufacturer's specification;

a. The oil pressure, flow of cooling water through open-circuit cooling systems, or the water level in the primary circuit of closed-circuit cooling systems, all meet the design and/or manufacturer's specification. The engine restarts using the manual start test button;

b. The electrolyte level and density of all lead acid cells meet the design and/or manufacturer's specification. If the density is low the battery charger should be checked for efficient operation and if the charger is working correctly the affected cells should be replaced;

- The stop valves which control the flow of water to the sprinkler systems from the water supply are in the correct position and any monitoring systems are working correctly;
- There is continuity of connection between the alarm switch and the control unit and between the control unit and the fire and rescue service for alarm systems which are automatically monitored by the emergency service provider;
- Trace heating systems provided to prevent freezing in the sprinkler systems are

functioning properly

- c. Check any smoke control systems provided for means of escape by simulating actuation of the system. Ensure that any fans and powered exhaust ventilators operate correctly, smoke dampers close, natural exhaust ventilators open, automatic smoke curtains move into position, etc.
- d. Check fire hydrants once a week to ensure that there are no obstructions which may impede access, that the indicator plates are in position and visible and that the isolating valves are locked open.

Sprinkler Systems

An automatic fire suppression system should be provided in accordance with the relevant standards⁷. It is recommended that the systems should be installed and maintained by a contractor who carries appropriate third party accreditation.

Fire-fighting water can be supplied from one of the following sources:

- City mains water supply: The agreement of the water authority is usually required for a city mains connection. Where water quality is poor, strainers must be fitted on all connections to the mains supply.
- Storage tanks: This can be a pump suction tank, gravity tank or reservoir.
- Inexhaustible sources: This includes lakes or rivers.
- Pressure tanks.

The relevant hazard classification of the system for use in high bay pharmaceutical warehouses is typically defined as 'ordinary hazard' (OH1 (BS EN 12845) or OH2 (NFPA).

Wet pipe sprinklers should be used in high bay warehouses – this means that the sprinkler network is fully charged with water at all times. The use of the alternative dry pipe system could result in an unacceptable time delay between the activation of a bulb and the flow of water through the sprinkler head.

Where the goods are stored in pallet racks the provision of in-rack sprinklers as well as roof level sprinklers is recommended. The sprinkler bulbs in the in-rack sprinkler heads activate at a much lower temperature than those at roof level; consequently the fire-fighting water is discharged in a more localized area. This means that the fire can be contained with a lower amount

of water damage than would be expected from the discharge of roof level sprinklers.

In cold climates, the installation may require protection against freezing if the pipe work passes through unheated spaces. Freeze-protection can be achieved using anti-freeze liquid or electrical trace heating. Where sprinklers are installed in cold rooms or freezer rooms, dry pendant drops should be used. With this arrangement, sections of dry pipe serve the relevant risk area and the actual flow valves are located outside the cold store. This prevents the water in the system from freezing.

Smoke Ventilation systems

Automatic smoke vents are generally provided to assist means of escape from the building. By venting smoke build-up at high level, the occupants can escape from the building underneath the smoke layer in reasonably safe conditions. Additional manually operated smoke vents are generally provided to aid the fire and rescue service with smoke clearance once the fire has been extinguished.

Where both sprinkler systems and smoke vents are provided in a building the interaction between them must be carefully considered. Research by Factory Mutual in the early 1970s, which remains relevant, showed that the provision of automatically operating smoke vents can cause delays in the operation of sprinkler systems. The reason for this is that automatic smoke vents open when triggered by smoke, whereas sprinklers operate when heat is detected. As smoke is generally detected more quickly than heat, Factory Mutual concluded that sprinklers would perform more effectively if there were no vents. Their reasoning was that the building would fill with smoke; this creates low oxygen conditions which limits combustion, allowing the sprinklers to extinguish the fire more effectively.

However, where life safety is the predominant requirement and a smoke control solution is used to protect the escape routes within a building, current guidance requires the smoke vents to operate automatically; the vents will therefore activate before the sprinkler system.

Alternatively, if the fire service response time is short, and the sprinkler system is provided with fast response heads, the smoke ventilation system may be activated by the flows within the sprinkler supply.

Compartmentation

Buildings are often divided into compartments, enclosed in fire-resisting construction; this approach provides passive fire protection by inhibiting the spread of fire within the building. In order to comply with local Building Regulations, the size of individual compartment may have to be limited. Compartment size is determined by the overall size of the building, the number of stories and whether or not an automatic sprinkler system is provided.

Fire Prevention, Training and Control Procedure

Risk Assessment

The first step in fire prevention is to assess the risks and record them in a risk register. Review and assess the means by which a fire might start and spread, the potential consequences and the available approaches to risk mitigation. This includes day to day operations, risk associated with periodic building maintenance work and those arising from installing new equipment, or adopting new or changing techniques.

Fire Prevention

Set out below are the principles actions that need to be taken to monitor the behaviour of workers and prevent fires from occurring:

- Smoking is one of the greatest fire risk and it should be prohibited in all buildings and work places. Where there is no legal prohibition, smoking should only be allowed in designated smoking areas and fire-safe ashtrays and bins should be provided;
- Enforce good housekeeping practices, this include implementing routines for the regular removal and disposal of waste;
- Establish and maintain out-of-hours inspection and security procedures, including means of preventing arson;
- Carry out routine checks, inspections and tests, including monitoring of maintenance of heat generation equipment that could cause fire, chafing of cables, self-heating of cables due to electrical resistance and checks on fuel supplies and storage;
- Issue and control work permits and associated procedures;

- Instruct and supervise contractors and sub-contractors carrying out construction and maintenance operations within the building;
- Avoid conditions leading to gas and dust explosion hazards;
- Maintain integration with other systems (e.g. ventilation, communication).

Fire Safety Training

All employees should be given fire safety training by a person who is competent in the subject and who understands effective training methods. If relevant expertise is not available within the organization, an independent expert –for example from fire brigade- should be engaged to provide training.

Fire safety training should start with induction training on the first day of new staff appointment. There should be refresher training at least once a year to ensure that all staff are familiar with the fire precautions for the workplace and are reminded of the actions to take in an emergency. More frequent training should be given where there is a high turnover of staff, or a high risk of fire.

All staff, including part-time staff, security staff, cleaning staff and contractors should be trained and instructed in:

- a. Risk awareness;
- b. Smoking policy;
- c. Basic fire prevention;
- d. Good housekeeping

The Fire Routine

- Actions to be taken when a fire is discovered or an alarm is heard
- Knowledge of the escape routes and exits, especially those not in regular use
- Raising the alarm and location of alarm indicator panels
- Arrangements for calling the fire and rescue services
- Special provision for assisting disabled people
- Selection and use of fire-fighting equipment (in large premises it may be appropriate to train specific staff instead of all staff)
- The importance of fire doors and the need to close all doors at the time of a fire and/or on

hearing the fire alarm

- Process shut down and shutting down of non-essential equipment, stopping machines and processes and isolating power supplies if appropriate
- Evacuation procedures.
- Incident reporting procedures, including for “near miss” events and false alarms. “No blame” reporting culture should be encouraged

Supervisory and other staffs who has specific responsibility for fire safety should receive detailed instruction in their own duties and appropriate refresher training at least once, and preferably twice a year. Staff with particular responsibilities is likely to include:

- Department heads;
- Fire marshals or fire wardens;
- Security staff (including night security patrols);
- Engineering and maintenance staff;
- Receptionists and telephone operators

Reducing Fuel Load

The amount of combustible material should be reduced, or stored more safely. Reduce the fire load. For example replace bottled gas heating with electric heating sources, or reduce the amount of bottled gas stored within the building