ODESA NATIONAL MEDICAL UNIVERSITY

DEPARTMENT OF ORGANIZATION AND ECONOMICS OF PHARMACY WITH POST-DIPLOMA SPECIALIZATION

TEXTS OF LECTURES ON OCCUPATIONAL SAFETY IN PHARMACY

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The lecture course "Occupational Safety in Pharmacy" is dedicated to studying the fundamental principles and safety requirements in the pharmaceutical industry. Students will learn about the regulatory and legal acts governing occupational safety, methods for preventing occupational diseases and injuries, as well as modern approaches to ensuring safe working conditions in pharmacies and pharmaceutical enterprises.

The course of lectures is built as a textbook that can be used in the training of specialists of the master's degree in specialty 226 "Pharmacy. Industrial Pharmacy"

ABBREVIATIONS

AIDS- acquired immunodeficiency syndrome

COVID-19- novel coronavirus infectious disease

IEC- information, education and communication

HIV- human immunodeficiency virus

ILO -International Labour Organization

IPC- infection prevention and control

NHS- National Health Service

OHS- occupational health and safety

OSH- occupational safety and health

PPE- personal protective equipment

SDG- Sustainable Development Goal

TB- tuberculosis

UN- United Nations

WASH- water, sanitation and hygiene

WHO- World Health Organization

GLOSSARY OF KEY TERMS AND DEFINITIONS

Accreditation: A formal process by which a recognized body, usually a nongovernmental organization, assesses and recognizes that a health care organization meets applicable predetermined and published standards. **Accreditation standards** are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organizations. An accreditation decision about a specific health care organization is made following a periodic on-site evaluation by a team of peer reviewers, which is typically conducted every two to three years. Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation

Employer: Any physical or legal person that employs one or more workers

Hazard: The inherent potential to cause injury or damage people's health

Health facility: A place where health services (i.e. not limited to medical or clinical services) are provided with the aim of contributing to improved health or to the diagnosis, treatment and rehabilitation of sick people

Health system: All organizations, institutions and resources that produce actions whose primary purpose is to improve health

Health workers: All people engaged in work actions whose primary intent is to improve health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, laboratory technicians, health technicians, medical and non-medical technicians, personal care workers, community health workers, healers and practitioners of traditional medicine. The term also includes health management and support workers such as cleaners, drivers, hospital administrators, district health managers and social workers, and other occupational groups in health-related activities as defined by the International Standard Classification of Occupations (ISCO-08)

Incident: An unsafe occurrence arising out of or in the course of work where no

personal injury is caused

Infection prevention and control: A practical, evidence-based approach that prevents patients and health workers from being harmed by avoidable infection and as a result of antimicrobial resistance

Joint Labour–management committee for health and safety: a bipartite body composed by equal number of representatives of the employer and health workers, which is established at the health facility to ensure cooperation between the employer and workers to achieve and maintain safe and healthy working conditions and environment

Risk: A combination of the likelihood of an occurrence of a hazardous event and the severity of injury or damage to people's health caused by this event

Risk assessment: The process of evaluating the risks to safety and health arising from hazards at work

Occupational health and safety (OHS) (occupational safety and health (OSH):A multidisciplinary area of work aiming at the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations; the prevention among workers of departures from health caused by their working conditions; the protection of workers in their employment from risks resulting from factors adverse to health; and the placing and maintenance of the worker in an occupational environment adapted to his physiological and psychological capabilities.

OSH management system: A set of interrelated or interacting elements to establish occupational health and safety policy and objectives, and to achieve those objectives. The system should contain the main elements of policy, organizing, planning and implementation, evaluation and action for improvement

Patient safety: A framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce impact of harm when it does occur (10).

Quality of care: The degree to which health services for individuals and populations increase the likelihood of desired health outcomes.

Safety culture: The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the characteristics of the organization's health and safety management. Organizations with a positive safety culture are characterized by communications based on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

Workers' representative: Any person who is recognized as such by national law or practice, whether they are: trade union representatives (namely, representatives designated or elected by trade unions or by members of such unions); or elected representatives (namely, representatives who are freely elected by the workers of the organization in accordance with provisions of national laws or regulations or of collective agreements and whose functions do not include activities that are recognized as the exclusive prerogative of trade unions in the country concerned)

LECTURE 1. BASIC LAWS AND REGULATIONS ON OCCUPATIONAL SAFETY AND HEALTH

1.History of workplace health and Safety

In today's safety-conscious world, it is hard to imagine a time when the well-being of employees wasn't a priority. But, in the not-too-distant past, health and safety was a new concept. In fact, it's taken over 200 years to evolve into the laws and guidance we have today.

Nowadays, in many areas of the world, health and safety continues to improve year on year, with fatality and injury numbers gradually decreasing. But health and safety wasn't always a priority for businesses and legislators. The health and safety legislation we see today has often been shaped by incidents that happened in the past.

In the UK, 28 fatalities at the Flixborough chemical plant in June 1974 was a catalyst for the formation of the Health and Safety Executive (HSE) and the introduction of the Health and Safety at Work Act 1974.

In the US, one of the most notorious incidents was The Triangle Shirtwaist Company fire in 1911, which killed 146 employees when they could not escape through locked doors. In the 1960s, 14,000 US workers were dying each year. In addition, 2.2 million were out of work due to injuries and illnesses. To tackle this crisis, in December 1970, President Nixon signed the OSH Act, which became law on April 28, 1971.

In Canada, the Hogg's Hollow disaster of March 1960, where five workers were killed by a fire and explosion whilst installing a water main, sparked a public outcry. This prompted the Ontario government to modernize safety regulations, leading to the enactment of the Industrial Safety Act in 1964.

The Industrial Revolution 1760 – 1800s . Before the Industrial Revolution began in 1760, it was the norm to make a living through agriculture or the making and selling of products from the home. With new developments in machinery and

manufacturing processes, Britain, followed by parts of Europe and the US, began moving towards a society fueled by mass production and the factory system.

People flocked to the cities for work where there were increased opportunities for employment in the new mills and factories. The vast number of people looking for work, and the need for cheap labour, led to poor pay, hazardous factory conditions and an increase in child Labour. Hours were long and conditions dangerous, with many losing their lives at work.

Work was particularly dangerous for children who would work from as young as 4 and sometimes over 12 hours a day. Many were used to climb under machinery which would often result in loss of limbs while others were crushed and some decapitated.

Girls working at match factories would develop phossy jaw from phosphorus fumes, children employed at glassworks were regularly burnt and blinded, while those working at potteries were vulnerable to poisonous clay dust. A lack of health and safety also meant that many children developed occupational diseases such as lung cancer, and died before the age of 25.

The Factory Act 1802.An outcry over child Labour conditions led to factory owner, Sir Robert Peel, introducing the Health and Morals of Apprentices Act 1802, commonly known as the Factory Act.

The Factory Act applied to all textile mills and factories employing three or more apprentices or twenty employees and required factories to;

- Have sufficient windows and opening for ventilation
- Be cleaned at least twice yearly with quicklime and water
- Limit working hours for apprentices to no more than 12 hours a day (excluding time taken for breaks)
- Stop night-time working by apprentices during the hours of 9pm and 6am
- Provide suitable clothing and sleeping accommodation to every apprentice

- Instruct apprentices in reading, writing, arithmetic and the principles of the Christian religion

While limited to a small portion of the workforce and with limited enforcement, the Factory Act is generally seen as the beginning of health and safety regulation.

The introduction of factory inspectors 1833-1868.Workers tired of spending over 12 hours a day in the factories, began a movement to reduce working days to 10 hours, known as the "Ten Hours Movement". Pressure from the group led to the Factory Act 1833.

The Act extended the 12 hours working limit to all children and included woolen and linen mills. Perhaps the most important development however, was the introduction of factory inspectors. The inspectors were given access to the mills and granted permission to question workers. Their main duty was to prevent injury and overworking of child workers but were also able to formulate new regulations and laws to ensure the Factories Act could be suitably enforced.

Despite only four inspectors being appointed for approximately 3,000 textile mills across the country, they were able to influence subsequent legislation relating to machinery guarding and accident reporting. A growing public interest in worker's welfare, influenced in part by popular writers such as Charles Dickens, saw inspector numbers grow to 35 in 1986. The type of workplaces they were able to enter also grew to cover the majority of workplaces.

The introduction of 'duty of care' in 1837. On May 30th 1835, Charles Priestley suffered a broken thigh, dislocated shoulder and several other injuries after a wagon cracked and overturned due to overloading by his employer, Thomas Fowler.

Priestly spent nineteen weeks recovering at a nearby inn, which cost him £50 (a considerable amount at the time). Priestly sued Fowler for compensation relating to the accident – the first documented case of an employee suing an employer over

work-related injuries. The jury awarded Priestley £100 in a landmark case which established the idea that employers owed their employees a duty of care.

However, an appeal of the case established that the employer is not responsible to ensure higher safety standards for an employee than he ensures for himself.

Safety regulations increase from 1842-1878. Several acts introduced over the next 36 years, saw protection towards women and children strengthen. Women and children were prevented from working in underground mines, the use of child labour to clean and maintain moving machinery was stopped, and a 56-hour work week for women and children was introduced.

The Employer's Liability Act 1880. In an attempt to correct the doctrine of Common Employment established following Priestly v. Fowler, the Employer's Liability Act enabled workers to seek compensation for injuries resulting from negligence of a fellow employee.

The act states that any worker or his family, are entitled to compensation for injury or death caused by a defect in equipment or machinery or negligence of a person given authority over the worker by the employer.

The Workmen's Compensation Act 1987, later removed the requirement that the injured party prove who for the injury, and are instead required only to prove that the injury occurred on the job.

A continued increase in acts and reforms 1880-1973. Health and safety continued to flourish, with a number of acts and reforms improving upon health and safety regulation across the country. Employers were required to provide safeguarding for machinery, the legal working age was gradually raised, and more and more inspectors were appointed across industries. In 1878 even saw the first safeguarding put in place for those working in the Agriculture industry, in regards to equipment, machinery and poisonous substances

Occupational Safety and Health Act 1970. Much like in the UK, mass production, the use of machinery and the availability of cheap Labour, meant that

health and safety was not always a major concern. In fact, it was cheaper to replace a dead or injured worker than to implement health and safety measures.

However, growing concern following World War II, soon led to the signing of the Occupational Safety and Health Act into US law. The legislation's main goal was to ensure employers provide employees with a work environment free from hazards including exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress and unsanitary conditions.

The act also led to the creation of the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH).

Health and Safety at Work Act 1974. In 1970, the Employed Persons (Health and Safety) Bill was introduced in the UK. However, the debate around the bill generated a belief that it did not address fundamental workplace safety issues. A committee of inquiry was established, and in 1974 the Health and Safety at Work Act was passed.

The Health and Safety at Work Act 1974 was a revolutionary piece of legislation that forms the basis of health and safety legislation across the world today.

Unlike previous acts in the UK, the Health and Safety as Work Act encompassed all industries and employees. The Act places responsibility on both the employer and employee to ensure the health, safety, and well-being of individuals across all workplaces, and members of the public who could be affected by work activities.

The act also led to the creation of the UK's Health and Safety Executive (HSE), which was put in place to regulate and reinforce UK legislation. Health and safety legislation continued to expand into the 90s, with the introduction of the Workplace Regulations 1992, which focused on basic health, safety, and welfare issues such as ventilation and cleanliness, and the Workplace Health and Safety Regulations 1999, which further clarified employer responsibilities.

Improvements in safety standards because of these legislations saw an incredible 73% reduction in the number of workplace fatalities between 1974 and 2007. Non-fatal injuries also fell by 70%

2019. The Health and Safety at Work Act 1974, still forms the basis of workplace safety law in the UK, and went on to influence legislation in Europe, New Zealand and other parts of the world. While the principles have largely remained the same, the Act continues to see updates and reforms alongside the evolution of the workplace and new health and safety challenges that arise.

Fortunately, the explosion of the internet and rapid developments in technology, has made managing health and safety in the workplace more efficient then it has ever been before.

2.Occupational Safety and Health Administration (OSHA)

Occupational safety and health (OSH) deals with all aspects of health and safety in the workplace. Its goal is to prevent the occurrence of occupational accidents and diseases. A safe and healthy working environment is one where risks are eliminated or when all reasonably practicable actions have been taken to reduce risks to an acceptable level and where prevention has been integrated as part of the organizations culture. Since its creation the ILO has been promoting occupational safety and health, and over the years has adopted about 40 Conventions and Recommendations specifically dealing with these issues. Employers have to comply with OSH laws and regulations. But management of occupational safety and health is not only a question of legal compliance.

There is a business case for safety and health at work. Good OSH performance can help ensure business continuity, preventing high levels of absence and avoiding losses of skilled workers. It can raise productivity and competitiveness as well as lead to reductions of insurance premiums. Additionally, health and safety investments can be justified on strategic grounds such as maintaining strong reputation to attract talent and preferred supply chain

relationships. Finally, managing OSH issues can be an opportunity to improve workplace cooperation and dialogue, boosting employee engagement.

To manage OSH efficiently companies focus on building a safety culture within the organization, employing risk management and control principles, aligning OSH management systems with other business operations, and involving workers in OSH managementt issues.
At the same time, employers are not the only ones involved in securing safety and health in the workplace. Workers and their representatives should cooperate with employers by taking reasonable care of their own safety, complying with the instructions given regarding safety and health, using protective equipment correctly and reporting any hazardous conditions or events and accidents. To promote compliance and good OSH performance, it is also key that employers are provided with support and guidance from relevant authorities. This is emphasized in the ILO Conventions 155 and 187. Micro and SMEs in particular may need help in complying with legal obligations and in developing OSH management processes.

The Occupational Safety and Health Administration (OSHA) assures safe and healthful working conditions by setting and enforcing standards, and by providing training, outreach, education and assistance.

OSHA's mission is to assure America's workers have safe and healthful working conditions free from unlawful retaliation. OSHA carries out its mission by setting and enforcing standards; enforcing anti-retaliation provisions of the OSH Act and other federal whistleblower laws; providing and supporting training, outreach, education, and assistance; and working collaboratively with our state OSHA programs as well as ensuring that they are at least as effective as federal OSHA, furthering a national system of worker safety and health protections.

OSHA is part of the United States Department of Labor. The administrator for OSHA is the Assistant Secretary of Labor for Occupational Safety and Health.

OSHA's administrator answers to the Secretary of Labor, who is a member of the cabinet

The National Institute for Occupational Safety and Health (NIOSH) is the federal institute responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (DHHS).

"NIOSH's mission is to develop and disseminate cutting-edge knowledge to improve workplace safety and health worldwide." NIOSH has the mandate to assure "every man and woman in the Nation safe and healthful working conditions and to preserve our human resources." The Occupational Safety and Health Act of 1970 established the National Institute for Occupational Safety and Health (NIOSH) as a research institute focused on the study of worker safety and health, and empowering employers and workers to create safe and healthy workplaces. It has more than 1,300 employees spread across the United States, from a diverse set of fields including epidemiology, medicine, nursing, industrial hygiene, safety, etc. NIOSH has nine centers that foster collaboration and research across NIOSH and with partners. This approach promotes strategic coordination of NIOSH's work.

3. Occupational safety in the healthcare system

Healthcare is involved, directly or indirectly, with the provision of health services to individuals. These services can occur in a variety of work settings, including hospitals, clinics, dental offices, out-patient surgery centers, birthing centers, emergency medical care, home healthcare, and nursing homes.

Healthcare workers face a number of serious safety and health hazards. They include blood borne pathogens and biological hazards, potential chemical and drug exposures, waste anesthetic gas exposures, respiratory hazards, ergonomic hazards from lifting and repetitive tasks, laser hazards, workplace violence, hazards associated with laboratories, and radioactive material and x-ray

hazards. Some of the potential chemical exposures include formaldehyde, used for preservation of specimens for pathology; ethylene oxide, glutaraldehyde, and paracetic acid used for sterilization; and numerous other chemicals used in healthcare laboratories.

More workers are injured in the healthcare and social assistance industry sector than any other. This industry has one of the highest rates of work related injuries and illnesses and it continues to rise. In 2020, the healthcare and social assistance industry reported a 40% increase in injury and illness cases which continues to be higher than any other private industry sector – 806,200 cases (2020 Survey of Occupational Injuries and Illnesses, BLS). Over half of these cases (447,890) resulted in at least one day away from work. The total incidence rate for this sector was 5.5 cases per 100 FTE workers in 2020, compared to 3.8 per 100 FTE workers in 2019.

Nursing assistants were amongst the occupations with the highest rates of musculoskeletal disorders of all occupations in 2020, with 15,360 cases. Musculoskeletal disorders made up 52% of all days away from work cases for nursing assistants.

In addition to the medical staff, large healthcare facilities employ a wide variety of trades that have health and safety hazards associated with them. These include mechanical maintenance, medical equipment maintenance, housekeeping, food service, building and grounds maintenance, laundry, and administrative staff.

All health workers have one main aim – to improve people's health. Health workers are the backbone of any functioning health system. While contributing to the enjoyment of the right to health for all, health workers should also enjoy the right to healthy and safe working conditions to maintain their own health. Unsafe working conditions are among the main reasons for strikes among health workers in low-income countries. Poor well-being and occupational burnout among health workers are associated with poor quality of care and negative patient safety

outcomes such as medical errors. Unsafe working conditions, stress, or the perceived lack of security in some countries, are among the main reasons for the attrition of health workers, exacerbating health workforce shortages.

Unsafe working conditions resulting in occupational illness, injuries and absenteeism, also represent a significant financial cost for the health sector. In 2017, for instance, the annual costs of the occupational illnesses and injuries in the health care and social services sector in Great Britain were the highest among all sectors, estimated at equivalent of US$ 3.38 billion. Improving health, safety and wellbeing of health workers lowers the costs of occupational harm (estimated at up to 2% of health spending) and contributes to minimizing patient harm (estimated at up to 12% of health spending). There are many international commitments, conventions and resolutions on healthy and safe working conditions for health workers. Respecting Labour rights and providing safe and healthy working environment for all workers, including health workers, is one of the global commitments under Sustainable Development Goal 8 on decent work and economic growth (SDG8.8).

At the United Nations (UN) High-level Meeting on Universal Health Coverage held at the 74th session of the UN General Assembly in 2019, all heads of state and governments committed to scale up efforts to promote healthier and safer workplaces, to increase the access of workers to occupational health services and to take action to improve the protection of health, safety and well-being of health workers.

In the 13th General Programme of Work of the World Health Organization (WHO), the Member States committed to pay special attention to decent working conditions for health workers. With Resolution WHA74.14 from 2021 on protecting, safeguarding and investing in the health and care workforce, the World Health Assembly called upon Member States “to take the necessary steps to safeguard and protect health and care workers at all levels, through the equitable distribution of personal protective equipment, therapeutics, vaccines and other

health services, effective infection prevention control and occupational safety and health measures within a safe and enabling work environment that is free from racial and all other forms of discrimination (23)".

Furthermore, at the 74th World Health Assembly in 2021, the global patient safety action plan 2021–2030 was adopted, which includes a strategic objective for health worker education, training and safety.

The International Labour Organization (ILO) Centenary Declaration on the Future of Work states that safe and healthy working conditions are fundamental to decent work. The ILO Promotional Framework for Occupational Safety and Health Convention, 2006 (No. 187) urges Member States to develop a national policy, national system and national programme on occupational safety and health, in coordination with other national programmes and plans.

Other ILO conventions relevant for protecting health and safety of health workers include the Occupational Safety and Health Convention, 1981 (No. 155), Protocol of 2002 to the Occupational Safety and Health Convention, 1981 and the Occupational Health Services Convention, 1985 (No. 161).

Furthermore, the Global call to action for a human centered recovery from the COVID-19 crisis that is inclusive, sustainable and resilient, adopted by the International Labour Conference in 2021, urges governments and social partners to ensure health workers and all other frontline workers have access to vaccines, personal protective equipment, training, testing and psychosocial support, and that they are adequately remunerated and protected at work, including against excessive workloads. Also, the ILO Nursing Personnel Convention of 1977 (No. 149) provides for adapting existing laws and regulations on occupational health and safety to the special nature of nursing work and of the environment in which it is carried out.

4.Occupational health and safety problems in the health sector.

The health care sector is composed of a web of institutions, occupational groups and diverse work environments. The exposure to occupational hazards

varies by settings, occupations and tasks. The most common occupational hazards for health workers are:

• Occupational infections – tuberculosis, hepatitis B and C, HIV, respiratory infections (e.g. coronaviruses, influenza) and vector-borne diseases (e.g. malaria, dengue).

• Ergonomic hazards – unsafe patient handling, heavy lifting, awkward postures causing back injury, chronic low back and neck pain and other musculoskeletal disorders.

• Hazardous chemicals – cleaning and disinfecting agents, mercury, latex allergy, toxic drugs, insecticides for vector control.

• Exposure to radiation – ionizing (x-rays and radionuclides) and non-ionizing (lasers, ultraviolet).

• Psychosocial hazard – time pressure, lack of control over work tasks, long working hours, shift work and lack of support.

• Violence and harassment – physical, sexual and psychological abuse and harassment at work.

• Risks in the ambient work environment – thermal discomfort (heat or cold stress) and noise.

• Injuries – slips, trips and falls, road traffic injuries (ambulance crashes, motorbike and bicycle injuries), electric shock, explosions, fire.

• Environmental health risks – inadequate water, sanitation and hygiene, health care waste, climate-related risks.

The exposure to occupational hazards is amplified by health worker shortages and misdistribution, lack of supportive supervision, poor building design and maintenance, lack of hygiene facilities and supplies, lack of training and information on occupational risks, the introduction of new ways of working and technologies, environmental change, and other issues.

LECTURE 2. GUARANTEES OF THE RIGHT TO OCCUPATIONAL SAFETY AND HEALTH.

1. Rights and responsibilities of employees and employers in Europe and the USA

Health and safety at work is one of the areas where the EU has had the biggest impact – with a solid legal framework covering the maximum number of risks with the minimum number of regulations. As set out by principle 10 of the European Pillar of Social Rights, workers have the right to a high level of protection of their health and safety at work.

They have the right to a working environment adapted to their professional needs and which enables them to prolong their participation in the labour market.

Legal basis.

Article 153 of the Treaty on the Functioning of the European Union gives the EU the authority to adopt legislation (directives) in the field of safety and health at work, in order to support and complement the activities of Member States.

Directive 89/391/EEC, the so-called occupational safety and health (OSH) "Framework Directive", lays down the main principles to encourage improvements in the safety and health of workers at work. It guarantees minimum safety and health requirements throughout the European Union while Member States are allowed to maintain or establish more stringent measures.

The Framework Directive is accompanied by further directives focusing on specific aspects of safety and health at work. Together they form the fundamentals of European safety and health legislation. Read more about specific OSH areas of activity.

Overview of EU OSH legislation:

- Framework Directive (Directive 89/391/EEC)
- Workplace requirements (Directive 89/654/EEC)
- Work equipment (Directive 2009/104/EC)
- Personal Protective Equipment (PPE) (Directive 89/656/EEC)
- Safety and/or health signs at work (Directive 92/58/EEC)

- Manual handling of loads (back injury) (Directive 90/269/EEC)
- Display screen equipment (Directive 90/270/EEC)
- Risks related to chemical agents at work (Directive 98/24/EC)
- Exposure to carcinogens or mutagens at work (Directive 2004/37/EC)
- Exposure to asbestos at work (Directive 2009/148/EC)
- Exposure to biological agents at work (Directive 2000/54/EC)
- Prevention from sharp injuries in the hospital and healthcare sector (Directive 2010/32/EU)
- Risks from explosive atmospheres (Directive 1999/92/EC)
- Risks arising from vibration (Directive 2002/44/EC)
- Risks arising from noise (Directive 2003/10/EC)
- Risks arising from artificial optical radiation (Directive 2006/25/EC)
- Risks arising from electromagnetic fields (Directive 2013/35/EU)
- Temporary or mobile construction sites (Directive 92/57/EEC)

Strategic and policy framework. To better protect workers in the EU from work-related accidents and diseases, the European Commission has adopted various strategic policy documents:

- The strategic framework on health and safety at work 2021-2027 identifies key objectives for health and safety at work, presents key actions and describes instruments to address these
- The Commission Communication "Safer and Healthier Work for All - Modernization of the EU Occupational Safety and Health Legislation and Policy", adopted on January 2017, proposes key actions in specific OSH priority areas.

All employers in the United States must comply with the General Duty Clause of the OSHA, which requires employers to keep the workplace free of recognized serious hazards.

1. Each employer: shall furnish to each of his employee's employment and a place of employment which are free from recognized hazards that are causing

or are likely to cause death or serious physical harm to his employees; shall comply with occupational safety and health standards promulgated under this

2. Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct.

2. Occupational health and safety programmes for health workers

The WHO–ILO Joint global framework for national occupational health programmes for health workers, adopted in 2010, provides strategic guidance for establishing the building blocks of occupational health and safety programmes at national and facility levels. The purpose of the national programmes is to ensure both the protection of the health and safety of health workers and the compliance of the health sector with national occupational health and safety regulations, while contributing to improving patient safety and the quality of patient care and providing opportunities for decent work in the health sector.

Key elements of national occupational health programmes for health workers according to the WHO–ILO joint global framework of 2010





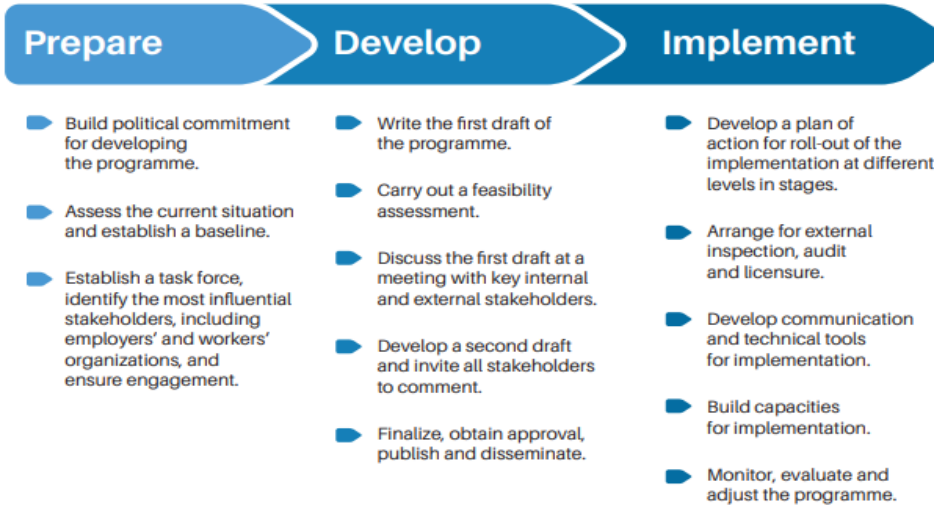


- Identify a responsible person with authority for occupational health at both the national and workplace levels.
- Develop a written policy on safety, health and working conditions for health workforce protection at the national and workplace levels.
- Ensure access to occupational health services by strengthening existing, or establishing new, occupational health programmes, and allocating sufficient resources to the programme, occupational health professional services, and the procurement of the necessary personal protective equipment and supplies.
- Create joint Labour–management health and safety committees with appropriate worker and management representation.
- Provide ongoing (or periodic) education and training that is appropriate to all parties, including occupational health practitioners, senior executives, front-line managers, health and safety committee, front-line workers and their representatives, and the general public.

- Identify hazards and hazardous working conditions in order to prevent and control them and manage risks by applying the occupational health hierarchy of controls, which prioritizes elimination or control at the source.
- Provide pre-service and ongoing immunizations against hepatitis B and other vaccine-preventable diseases in the workplace at no cost to the employee and ensure that all three doses of the hepatitis B immunization have been received by all workers at risk of blood exposure (including cleaners and waste handlers)
- Promote exposure and incident reporting, eliminating barriers to reporting and providing a blame-free environment.
- Promote and ensure health worker access to diagnosis, treatment, care and support for HIV, TB, hepatitis B and hepatitis C viruses.
- Utilize appropriate information systems to assist in the collection, tracking, analysis, reporting and acting upon data to promote health and safety of the health care workplace and health workforce.
- Ensure that health workers are provided with entitlement for compensation for work-related disability in accordance with national laws.
- Promote research on occupational health and safety issues of concern to health workers and translation of research into practice, particularly with respect to combined exposures and applied intervention effectiveness research.
- Promote and implement greening health sector initiatives that incorporate occupational health and green and safe jobs while reducing greenhouse gas emissions with a preference for: the use of renewable energy; providing safe drinking water; promoting hand hygiene; active transport; environmentally preferable management of hazardous health care waste; and environmentally preferable selection and disposal of chemicals such as pesticides, disinfectants and sterilants.

The development and implementation of occupational health and safety programs for healthcare workers are presented in Fig. 1

Figure 1. Development and implementation of occupational health and safety programmes for health workers



3. Principles for the development and implementation of occupational health and safety programmes in the health sector.

The development and implementation of programmes for occupational health and safety for health workers should take into consideration the following principles:

• Employers of health workers have the duty to implement occupational health and safety measures for the prevention of occupational and work-related diseases and injuries, while health workers, like all other workers, have the right to healthy and safe working conditions and the duty to comply with the instructions for health and safety and take reasonable care of their own safety).

• Occupational health and safety (OHS) measures require a system for management, continuous improvement and regular dialogue between employers, workers and their representatives and involvement of other stakeholders, such as professional associations of health workers and patient groups.

• The efficiency of the occupational health programmes can be increased by establishing synergies or banding with programmes targeting health workers and health facilities, such as programmes on the quality and safety of care,

including infection prevention and control (IPC) and patient safety, health workforce management, and environmental health.

• National and subnational programmes should aim to cover all health workers in all types of health facilities in public, private and nongovernmental settings as well as in health facilities with other forms of ownership and governance. Programmes in health facilities should also aim to include the health and safety of subcontractors, suppliers and also, where applicable, community health workers.

• The programmes at national, subnational and facility levels should be implemented in a sustainable way to ensure continuous protection of the health and safety of health workers at all times, including during public health and other emergency situations.

• The development and implementation of the programmes should be gender responsive, non-discriminatory and inclusive, taking into account the special needs of female health workers, migrant health workers, vulnerable groups and workers with precarious employment conditions

4. National programmes

At the national level, countries may have several national programmes that are related to protecting the health and safety of health workers. Many countries have comprehensive acts on health and safety at work and cross sectoral national programmes and systems developed in accordance with the ILO Promotional Framework for Occupational Safety and Health Convention, 2006 (No. 187).

Programmes for occupational health and safety for health workers have to be aligned with the existing general national legislations, regulations, policies, programmes and systems concerning health and safety at work. Other programmes within the health sector may also aim at addressing different aspects of the health and safety of health workers, such as:

• Health care quality and safety – quality of health services, patient safety, IPC

• National programmes for immunization.

• Disease control programmes – tuberculosis (TB), human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) and viral hepatitis, including intervention for providing specific services for health workers to prevent and control the spread of these diseases among the health workforce.

• Health workforce management in terms of staffing levels, skills development, work organization, supervision, and education and training.

• Environmental health – climate-resilient and environmentally sustainable health services, water and sanitation, health care waste management, safe use of chemicals and radiation.

Therefore, it may be efficient to coordinate the delivery of interventions, procurement, planning, reporting and capacity-building for occupational health and safety with other national health programmes targeting health workers and health facilities to avoid duplication, overlapping and misalignment and to increase efficiency in the use of resources. WHO recommends that the planning and delivery of health programmes is organized according to the basic functions of health systems – stewardship/ governance, generation of human and physical resources/inputs, financing, and service delivery.

Governance and stewardship

- A national policy statement on occupational health and safety for health workers is issued at the highest possible level and communicated at all levels of workplaces in all management and practice environments in the health sector.
- A unit is designated at the national level to take charge of the occupational health and safety of health workers.
- A multistakeholder Steering Committee for health and safety in the health sector is established at national level to oversee and steer programme implementation. Regulations and standards for prevention and control of the most common

occupational health hazards in the health sector are available in all health facilities.

- A set of key indicators for monitoring programme implementation at the national, subnational and facility levels is available and integrated into the national health information system.

For the purpose of the occupational health and safety programmes, governance and leadership are the ways the health system is run and how the institutions involved in it, both public and private, are overseen in order to ensure adequate level of protection of health and safety of health workers.

This requires the setting of objectives and directions, planning and monitoring, and regulating occupational health and safety in the health sector, as well as collecting information and using it for identifying related trends and monitoring and evaluating performance. The following elements of occupational health and safety programmes for health workers aim at strengthening governance and stewardship.

LECTURE 3. ACCIDENTS AND OCCUPATIONAL DISEASES OF PHARMACEUTICAL WORKERS

1. Maintaining improved health and safety standards in the pharmaceutical industry

Workplace-related health impairments, injuries and illnesses cause great human suffering and incur high costs, both for those affected and for society as a whole. Occupational health and safety measures and health promotion in workplaces are aimed at preventing this.

According to the World Health Organisation (WHO) definition of health is state of complete physical, mental and social well-being, as well as the empowerment of individuals to use their own health potential and to deal successfully with the demands of their environment.

Health and safety are an integral component of workforce sustainability and improved productivity in the pharmaceutical industry. The pharmacists are

constantly being exposed to chemical and biological hazards which pose a serious threat to their health. Furthermore, lack of adequate safety standards and non-compliance may impact workforce productivity and have significant repercussions on business sustenance in the long run. Therefore, it is important to have optimal health and safety practices while ensuring that all employees adhere to such regulations.

Maintaining improved health and safety standards in the pharmaceutical industry involves several steps:

Risk Evaluation

Effective risk evaluation is the cornerstone of assessing the potential hazards at workplace and ensuring safety of the employees. In the pharmaceutical industry, it is legally obligatory to conduct thorough health and safety risk estimation. It involves reviewing the workplace to identify the dangers and their sources. Typically, the following steps are involved in health and safety risk assessment:

- Walk around the facility to discover potential risks and evaluate the accident record sheets
- Once the dangers are identified, check which employees are most vulnerable to such threats
- Determine how the workplace hazards can be managed and control; set a definitive action plan – the objective must be to either minimise or remove the hazard to ensure improved health and safety of the employees
- Record the risks and action taken to demonstrate the issue has been identified and given attention
- Review the risk evaluation report annually to ensure effective implementation of health and safety measures in the workplace

Practice Primary Laboratory Safety

In the pharmaceutical industry, maintaining basic safety in the laboratory is mandatory. The Occupational Safety and Health Administration (OSHA) have

comprehensive guidelines regarding how to practice lab safety. Ensure all your employees are aware of the primary health and safety practices and take preventive measures when working in a hazard-prone environment.

Based on OSHA guidelines, the following key steps can be taken to maintain health and safety at the laboratory:

- Practice frequent cleaning, particularly when the employees are exposed to chemical hazards or particles
- Wash hands regularly and properly to inhibit the spread of bacteria, viruses or hazardous chemicals
- Never eat, drink or smoke inside the laboratory
- Make wearing suitable Personal Protective Equipment mandatory inside the laboratory – coveralls, eye gear, protective helmet, shoe covers, etc.
- Label the containers appropriately
- Regularly check that all equipment is working properly and safe to use
- Wear head cap to prevent contamination through hair
- Keep the corridors clean and sanitized
- Perform risk evaluations every day

Ensure Injury Free Work Environment

For any pharmaceutical company, employees are the biggest asset. To ensure their improved health and safety, it is important to implement and regulate an "injury free" environment. Set guidelines, take action and regulate implementation of safety measures that eliminate injuries and incidents.

Some of the key steps here are:

- ✓ Visibly demonstrate and inspire through your commitment to inculcate an injury and incident free culture.
- ✓ Educate employees that they are accountable for their own safety and also for the safety of those around them.

- ✓ Implement effective management that helps identify, control and eliminate all types of hazards up to an acceptable limit.
- ✓ Take appropriate action to prevent the reoccurrence of incidents and injuries through effective investigation and anticipatory strategy development
- ✓ Implement and regulate corporate safety standards across all your pharmaceutical buildings, offices and laboratories
- ✓ Conduct injury-free survey wherever appropriate to discover opportunities for improvements

Health & Safety Standards in Handling Chemicals

Transporting and handling hazardous chemicals can be dangerous. If done inappropriately by untrained staff, it can cause chemical releases, explosions and fire. To minimize the risk and ensure more safety, it should be done “so far as is reasonably practicable.” Using the Classification of Chemicals can be an effective way of handling hazardous chemicals and mitigating the associated risks.

The Classification of Chemicals helps identify how the chemicals can have detrimental effects. It also states how the chemicals should be labelled correctly and handled in a legally-compliant manner to avoid disasters or health risks. High temperature, high pressure or oxidation often causes chemicals to explode or release. By lowering the oxidation work scale and understanding the right flammable limits, pharmaceutical companies can help reduce the risks.

Installing emergency showers is also an effective way of handling chemicals when they come directly into contact with the user. It can help wash away the chemical from the PPE and the skin to prevent health hazards. Consider installing eye wash stations inside the facility to minimize the risk of major damages.

2. Accident and incident in the workplace

The term «incident» can be defined as an occurrence, condition, or situation arising in the course of work that resulted in or could have resulted in injuries, illnesses, damage to health, or fatalities. The term "accident" is also commonly

used, and can be defined as an unplanned event that interrupts the completion of an activity, and that may (or may not) include injury or property damage. Some make a distinction between accident and incident. They use the term incident to refer to an unexpected event that did not cause injury or damage that time but had the potential. "Near miss" or "dangerous occurrence" are also terms for an event that could have caused harm but did not.

Please note: The term incident is used in some situations and jurisdictions to cover both an "accident" and "incident". It is argued that the word "accident" implies that the event was related to fate or chance. When the root cause is determined, it is usually found that many events were predictable and could have been prevented if the right actions were taken - making the event not one of fate or chance (thus, the word incident is used). For simplicity, we will now use the term incident to mean all of the above events.

Reasons to investigate a workplace incident include:

- most importantly, to find out the cause of incidents and to prevent similar incidents in the future
- to fulfill any legal requirements
- to determine the cost of an incident
- to determine compliance with applicable regulations (e.g., occupational health and safety, criminal, etc.)
- to process workers' compensation claims

The same principles apply to an inquiry of a minor incident and to the more formal investigation of a serious event. Most importantly, these steps can be used to investigate any situation (e.g., where no incident has occurred ... yet) as a way to prevent an incident.

Workplace incident investigation. Ideally, an investigation would be conducted by someone or a group of people who are:

- experienced in incident causation models,
- experienced in investigative techniques,
- knowledgeable of any legal or organizational requirements,
- knowledgeable in occupational health and safety fundamentals,

- knowledgeable in the work processes, procedures, persons, and industrial relations
- environment for that particular situation,
- able to use interview and other person-to-person techniques effectively (such as
- mediation or conflict resolution),
- knowledgeable of requirements for documents, records, and data collection; and
- able to analyze the data gathered to determine findings and reach recommendations.
- Some jurisdictions provide guidance such as requiring that the incident must be conducted
- jointly, with both management and Labour represented, or that the investigators must be
- knowledgeable about the work processes involved

Members of the team can include:

- employees with knowledge of the work
- supervisor of the area or work
- safety officer
- health and safety committee
- union representative, if applicable
- employees with experience in investigations
- "outside" experts
- representative from local government or police

Note: In some cases, other authorities may have jurisdiction, such as if a serious injury or fatality occurred. Your organization should establish, implement, and maintain a procedure to coordinate managing incidents with the authority having jurisdiction (e.g., police, OH&S inspectors, etc.). This coordination may include the authority taking control of the incident scene.

The presence of the line manager in the investigation of a workplace incident

The advantage is that this person is likely to know most about the work and persons involved and the current conditions. Furthermore, the supervisor can

usually take immediate remedial action. The counter argument is that there may be an attempt to gloss over the supervisor's shortcomings in the incident. This situation should not arise if the incident is investigated by a team of people, and if the worker representative(s) and the investigation team members review all incident investigation findings and recommendations thoroughly.

An investigator or team who believe that incidents are caused by unsafe conditions will likely try to uncover conditions as causes. On the other hand, one who believes they are caused by unsafe acts will attempt to find the human errors that are causes. Therefore, it is necessary to examine all underlying factors in a chain of events that ends in an incident. The important point is that even in the most seemingly straightforward incidents, seldom, if ever, is there only a single cause. For example, an "investigation" which concludes that an incident was due to worker carelessness, and goes no further, fails to find answers to several important questions such as:

- Was the worker distracted? If yes, why was the worker distracted?
- Was a safe work procedure being followed? If not, why not?
- Were safety devices in order? If not, why not?
- Was the worker trained? If not, why not?
- An inquiry that answers these and related questions will probably reveal conditions that are more open to correction.

The steps involved in investigating an incident

First:

- Report the incident occurrence to a designated person within the organization.
- Provide first aid and medical care to injured person(s) and prevent further injuries or damage.

The incident investigation team would perform the following general steps:

- Scene management and scene assessment (secure the scene, make sure it is safe for investigators to do their job).

- Witness management (provide support, limit interaction with other witnesses, interview).
- Investigate the incident, collect data.
- Analyze the data, identify the root causes.
- Report the findings and recommendations.

The organization would then:

- Develop a plan for corrective action.
- Implement the plan.
- Evaluate the effectiveness of the corrective action.
- Make changes for continual improvement.

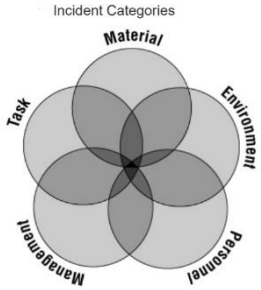
As little time as possible should be lost between the moment of an incident and the beginning of the investigation. In this way, one is most likely to be able to observe the conditions as they were at the time, prevent disturbance of evidence, and identify witnesses. The tools that members of the investigating team may need (pencil, paper, camera or recording device, tape measure, etc.) should be immediately available so that no time is wasted.

The cause of an incident

Causation Models

Many models of causation have been proposed, ranging from Heinrich's domino theory to the sophisticated Management Oversight and Risk Tree (MORT). The simple model shown in Figure 2 attempts to illustrate that the causes of any incident can be grouped into five categories - task, material, environment, personnel, and management.

When this model is used, possible causes in each category should be investigated.



Task

Here the actual work procedure being used at the time of the incident is explored. Members of the investigation team will look for answers to questions such as:

- Was a safe work procedure used?
- Had conditions changed to make the normal procedure unsafe?
- Were the appropriate tools and materials available?
- Were they used?
- Were safety devices working properly?
- Was lockout used when necessary?

For most of these questions, an important follow-up question is "If not, why not?"

Material

To seek out possible causes resulting from the equipment and materials used, investigators might ask:

- Was there an equipment failure? What caused it to fail?
- Was the machinery poorly designed?
- Were hazardous products involved?
- Were they clearly identified?
- Was a less hazardous alternative product possible and available?
- Was the raw material substandard in some way?
- Should personal protective equipment (PPE) have been used?
- Was the PPE used?
- Were users of PPE properly educated and trained?

Again, each time the answer reveals an unsafe condition, the investigator must ask why this situation was allowed to exist.

Work Environment

The physical work environment, and especially sudden changes to that environment, are factors that need to be identified. The situation at the time of the incident is what is important, not what the "usual" conditions were. For example, investigators may want to know:

- What were the weather conditions?

- Was poor housekeeping a problem?
- Was it too hot or too cold?
- Was noise a problem?
- Was there adequate light?
- Were toxic or hazardous gases, dusts, or fumes present

Personnel

The physical and mental condition of those individuals directly involved in the event must be explored, as well as the psychosocial environment they were working within. The purpose for investigating the incident is not to establish blame against someone but the inquiry will not be complete unless personal characteristics or psychosocial factors are considered. Some factors will remain essentially constant while others may vary from day to day:

- Did the worker follow the safe operating procedures?
- Were workers experienced in the work being done?
- Had they been adequately educated and trained?
- Can they physically do the work?
- What was the status of their health?
- Were they tired?
- Was fatigue or shiftwork an issue?
- Were they under stress (work or personal)?
- Was there pressure to complete tasks under a deadline, or to by-pass safety procedures?

Management

Management holds the legal responsibility for the safety of the workplace and therefore the role of supervisors and higher management and the role or presence of management systems must always be considered in an incident investigation. These factors may also be called organizational factors. Failures of management systems are often found to be direct or indirect causes. Ask questions such as:

- Were safety rules or safe work procedures communicated to and understood by all employees?

- Were written procedures and orientation available?
- Were the safe work procedures being enforced?
- Was there adequate supervision? Were workers educated and trained to do the work?
- Had hazards and risks been previously identified and assessed?
- Had procedures been developed to eliminate the hazards or control the risks?
- Were unsafe conditions corrected?
- Was regular maintenance of equipment carried out?
- Were regular safety inspections carried out?
- Had the condition or concern been reported beforehand? Was action taken?

Fact collection

The steps in the investigation are simple: the investigators gather data, analyze it, determine their findings, and make recommendations. Although the procedures are seemingly straightforward, each step can have its pitfalls. As mentioned above, an open mind is necessary in an investigation: preconceived notions may result in some wrong paths being followed while leaving some significant facts uncovered. All possible causes should be considered. Making notes of ideas as they occur is a good practice but conclusions should not be made until all the data is gathered.

Physical Evidence

Before attempting to gather information, examine the site for a quick overview, take steps to preserve evidence, and identify all witnesses. In some jurisdictions, an incident site must not be disturbed without approval from appropriate government officials such as the coroner, inspector, or police. Physical evidence is probably the most non-controversial information available. It is also subject to rapid change or obliteration; therefore, it should be the first to be recorded. Based on your knowledge of the work process, you may want to check items such as:

- positions of injured workers
- equipment being used
- products being used
- safety devices in use
- position of appropriate guards
- position of controls of machinery
- damage to equipment
- housekeeping of area
- weather conditions
- lighting levels
- noise levels
- time of day

You may want to take photographs before anything is moved, both of the general area and specific items. A later study of the pictures may reveal conditions or observations that were missed initially. Sketches of the scene based on measurements taken may also help in later analysis and will clarify any written reports. Broken equipment, debris, and samples of materials involved may be removed for further analysis by appropriate experts. Even if photographs are taken, written notes about the location of these items at the scene should be prepared.

Witness Accounts

Although there may be occasions when you are unable to do so, every effort should be made to interview witnesses. In some situations, witnesses may be your primary source of information because you may be called upon to investigate an incident without being able to examine the scene immediately after the event. Because witnesses may be under severe emotional stress or afraid to be completely open for fear of recrimination, interviewing witnesses is probably the hardest task facing an investigator.

Witnesses should be kept apart and interviewed as soon as possible after the incident. If witnesses have an opportunity to discuss the event among

themselves, individual perceptions may be lost in the normal process of accepting a consensus view where doubt exists about the facts.

Witnesses should be interviewed alone, rather than in a group. You may decide to interview a witness at the scene where it is easier to establish the positions of each person involved and to obtain a description of the events. On the other hand, it may be preferable to carry out interviews in a quiet office where there will be fewer distractions. The decision may depend in part on the nature of the incident and the mental state of the witnesses

Interviewing

The purpose of the interview is to establish an understanding with the witness and to obtain his or her own words describing the event:

DO...

- put the witness, who is probably upset, at ease
- emphasize the real reason for the investigation, to determine what happened and why
- let the witness talk, listen
- confirm that you have the statement correct
- try to sense any underlying feelings of the witness
- make short notes or ask someone else on the team to take them during the interview
- ask if it is okay to record the interview, if you are doing so
- close on a positive note

DO NOT...

- intimidate the witness
- interrupt
- prompt
- ask leading questions
- show your own emotions
- jump to conclusions

Ask open-ended questions that cannot be answered by simply "yes" or "no". The actual questions you ask the witness will naturally vary with each incident, but there are some general questions that should be asked each time:

- Where were you at the time of the incident?
- What were you doing at the time?
- What did you see, hear?
- What were the work environment conditions (weather, light, noise, etc.) at the time?
- What was (were) the injured worker(s) doing at the time?
- In your opinion, what caused the incident?
- How might similar incidents be prevented in the future?

Asking questions is a straightforward approach to establishing what happened. But, care must be taken to assess the accuracy of any statements made in the interviews. Another technique sometimes used to determine the sequence of events is to re-enact or replay them as they happened. Care must be taken so that further injury or damage does not occur. A witness (usually the injured worker) is asked to reenact in slow motion the actions that happened before the incident.

Making the analysis and recommendations

At this stage of the investigation most of the facts about what happened and how it happened should be known. This data gathering has taken considerable effort to accomplish but it represents only the first half of the objective. Now comes the key question - why did it happen? Keep an open mind to all possibilities and look for all pertinent facts.

There may still be gaps in your understanding of the sequence of events that resulted in the incident. You may need to re-interview some witnesses or look for other data to fill these gaps in your knowledge. When your analysis is complete, write down a step-by-step account of what happened (the team’s conclusions) working back from the moment of the incident, listing all possible causes at each step. This is not extra work: it is a draft for part of the final report. Each conclusion

should be checked to see if: it is supported by evidence the evidence is direct (physical or documentary) or based on eyewitness accounts, or the evidence is based on assumption. This list serves as a final check on discrepancies that should be explained.

The most important final step is to come up with a set of well-considered recommendations designed to prevent recurrences of similar incidents. Recommendations should:

- be specific
- be constructive
- identify root causes
- identify contributing factors

Resist the temptation to make only general recommendations to save time and effort. For example, you have determined that a blind corner contributed to an incident. Rather than just recommending "eliminate blind corners" it would be better to suggest:

- install mirrors at the northwest corner of building X (specific to this incident)
- install mirrors at blind corners where required throughout the worksite (general)

Never make recommendations about disciplining a person or persons who may have been at fault. This action would not only be counter to the real purpose of the investigation, but it would jeopardize the chances for a free flow of information in future investigations. In the unlikely event that you have not been able to determine the causes of an incident with complete certainty, you probably still have uncovered weaknesses within the process, or management system. It is appropriate that recommendations be made to correct these deficiencies.

The Written Report

The prepared draft of the sequence of events can now be used to describe what happened. Remember that readers of your report do not have the intimate

knowledge of the incident that you have so include all relevant details, including photographs and diagrams. Identify clearly where evidence is based on certain facts, witness accounts, or on the team's assumptions.

If doubt exists about any particular part of the event, say so. The reasons for your conclusions should be stated and followed by your recommendations. Do not include extra material that is not required for a full understanding of the incident and its causes such as photographs that are not relevant and parts of the investigation that led you nowhere. The measure of a good report is quality, not quantity.

Always communicate your findings and recommendations with workers, supervisors and management. Present your information 'in context' so everyone understands how the incident occurred and the actions needed to put in place to prevent it from happening again.

Some organizations may use pre-determined forms or checklists. However, use these documents with caution as they may be limiting in some cases. Always provide all of the information needed to help others understand the causes of the event, and why the recommendations are important.

- Follow-up actions include:
- Respond to the recommendations in the report by explaining what can and cannot be done (and why or why not).
- Develop a timetable for corrective actions.
- Monitor that the scheduled actions have been completed.
- Check the condition of injured worker(s).
- Educate and train other workers at risk.
- Re-orient worker(s) on their return to work.

LECTURE 4. OCCUPATIONAL RISKS IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry faces at least five distinct hazards that employers and employees should be aware of:

1. Flammable and Combustible Materials

Combustible and flammable materials present within pharmaceutical manufacturing facilities can cause uncontrolled fires, leading to extensive and often costly property damage. Accidents involving flammable materials can also lead to serious and potentially fatal worker injury (e.g., burns, smoke inhalation).

2. Hazardous Chemicals

Working with, handling, transporting, and storing chemicals is a primary component of the pharmaceutical manufacturer's workday. Many chemicals used in both primary and secondary processing can be extremely hazardous to human health if accidentally ingested or inhaled.

3. Biological Hazards

The pharmaceutical industry continues to make rapid advances in the prevention and treatment of infectious pathogens, including bacteria, viruses, and fungi. To drive this innovation, pharmaceutical workers, scientists, and researchers must routinely handle these hazardous organisms, along with any chemicals and materials needed for the development of vaccines and other types of medicines.

To reduce the risk of accidental exposure to biological hazards, tightly controlled primary and secondary containment methods should be utilized. These methods include even the simplest strategies, such as routine handwashing, up to and including advanced ventilation systems.

4. Carbon Monoxide Exposure

Carbon monoxide can develop as a byproduct of certain chemical reactions. This odorless and colorless gas is toxic to humans and can cause dizziness, weakness, vomiting, and even death when inhaled. Protecting workers from carbon monoxide and other toxic fumes should include the use of (and regular inspection of) carbon

monoxide detectors and appropriate signage wherever this gas is stored or potentially created.

5. UV Radiation

We typically think of ultraviolet (UV) radiation in the context of sunlight. However, the pharmaceutical manufacturing industry may use UV radiation for operations such as vitamin D production. Excessive exposure to UV radiation has been associated with an increased risk of cataracts, skin cancer, and burns on the eyes and skin. When applicable, pharmaceutical workers should be offered apparel and accessories that can protect their eyes and skin from UV light.

6. Ergonomic Hazards

A pharmacy workplace setting should enable workers to move freely and with ease. Additionally, equipment needed for the job, such as computers, should be adjusted accordingly. Providing seating options and designing shelves to make access to medications easier also can improve the health and safety of pharmacists. Pharmacists rely on computers to do their job; therefore, adjustments should be made to make them user friendly. For instance, screen brightness should be adjusted so it doesn't hurt the eyes. Plus, where and how it is accessed should also be considered.

Materials that are non-slippery should be used on the floors to avoid slips, trips, and falls. Adequate lighting—but not glaring— should be provided for improved depth perception.

7. Physical Hazards.

Cuts are one of the most common pharmacy injuries. Sharp instruments (medical instruments, scalpels, and scissors), broken glassware, equipment, and tool use can all contribute to cuts. But these risks can be avoided, or at least minimized, with proper worker education and the implementation of safe work procedures. After using any equipment or tool, it should be put back in a location where it won't cause any trouble. Wearing protective clothing and gear should also be required.

Burns are another physical injury pharmacist can sustain, especially by those who work with heat sealers. When dealing with such machines, education plays an important role in reducing injuries.

Electrical cords and appliances are widely used in pharmacies, but can also be hazardous. Proper placement of circuits away from elements that pose a danger should be implemented, as should the grounding of fault circuit interrupters when used near water sources.

8. Psychological Hazards

Long hours and an excessive workload are issues pharmacists are subject to, and can be remedied by changing management policies and procedures. Changes can also be made in the work environment, such as providing adjustable lighting, designing a workplace to improve alertness, and setting an appropriate thermal environment.

Pharmacists can also be subject to abuse by clients or fellow co-workers. Workers should be educated about violence awareness and avoidance, and know procedures for de-escalation. Management should also address troubles promptly.

Personal Protective Equipment (PPE) in the Pharmaceutical Industry

It is important to consider that the health and safety hazards typical of the pharmaceutical manufacturing industry can affect individuals other than direct staff. Due to issues such as cross-contamination and accidental environmental exposure, workers within the pharmaceutical manufacturing industry can unintentionally expose their families, fellow community members, and domesticated and wild animals to toxic or otherwise harmful materials.

To reduce this risk of accidental exposure both inside and outside the workplace, it is imperative for company leaders within this industry to make safety their leading priority. Company leaders should establish protocols that help standardize and streamline safety procedures. When relevant, safety protocols should also comply with local and national regulatory boards, including the Occupational Health and Safety Administration (OSHA).

Recommended pharmaceutical PPE varies considerably, but generally includes:

- Protective apparel, including gowns and coveralls
- Gloves
- Shoe covers
- Eye protection, including face masks and goggles
- Respiratory protection, which includes N95 respirators and powered air-purifying respirators (PAPR)

Employers should always ensure their workforce has access to high quality and durable pharmaceutical PPE that provides adequate protection without impairing worker mobility, gross motor function, vision, productivity, and general comfort. It is also the employer's responsibility to ensure that all personnel are thoroughly trained on how to properly don, doff, store, and if necessary, dispose of PPE to further mitigate the risk of hazardous conditions or exposure

Potential Hazards and Recommended Controls

Biological Hazards and Controls

Employers should carefully evaluate the potential for exposure to biohazardous materials in all tasks and ensure that they have an effective hazard control plan in place.

Biological agents are widely found in the natural environment and as a result found in many work sectors. They include bacteria, viruses, fungi (including yeasts and molds) and internal human parasites (endoparasites). The majority of these agents are harmless however some may have potential to cause ill health.

The Effects of Biological Agents

As they are usually invisible, it is often difficult to appreciate the risks they present. As a worker you may be harmed by:

- being infected by a biological agent,
- being exposed to toxins produced by the biological agent, or
- having an allergic reaction to the biological agent or substances it produces, for example, enzymes.

Biological agents have the ability to replicate rapidly, require minimal resources to survive and can infect at very small doses.

Types of Exposure

In the workplace, exposure to biological agents can be:

- intentional, whereby the employee works directly with them, for example, in a laboratory or research facility;
- unintentional, whereby the employee is exposed to the biological agent due to the work they do, for example, a healthcare worker who is exposed to a blood borne virus,

Classification of Biological Agents

Biological Agents are classified in the Code of Practice to the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020, into four risk groups – groups 1, 2, 3 and 4.

Agents are classified into 4 risk groups according to their level of risk of infection and can relate to bacteria, fungi, virus, parasites etc. These groups are:

- A "group 1 biological agent", means one that is unlikely to cause human disease to employees.
- A "group 2 biological agent", means one that can cause human disease and might be a hazard to employees, although it is unlikely to spread to the community and in respect of which, there is usually effective prophylaxis or treatment available.
- A "group 3 biological agent" means one that can cause severe human disease and presents a serious hazard to employees and which may present a risk of spreading to the community, although there is usually effective prophylaxis or treatment available.
- A "group 4 biological agent" means one that causes severe human disease and is a serious hazard to employees and which may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available.

What hygiene and individual protection measures should be taken when working with biological agents?

In the case of any activity in relation to which there is a risk to the safety or health of employees caused by working with a biological agent, the employer must take appropriate measures to ensure that:

- Employees do not eat or drink in any location within a place of work where there is a risk of contamination by a biological agent
- Employees are provided with suitable washing and toilet facilities, which may include eye washes and skin antiseptics (or both)
- Employees are provided with suitable personal protective equipment (PPE)
  - ✓ Any necessary PPE is: properly stored in a designated place checked and cleaned if possible, before, and in any case after each use
  - ✓ repaired, where defective, or replaced, before further use

Procedures are specified for taking, handling and processing samples of human or animal origin

Working clothes and PPE, which may be contaminated by a biological agent, are removed on leaving the working areas and, before taking measures for cleaning/decontaminating/destroying, kept separately from other clothing

The working clothes and PPE are decontaminated and cleaned or, if necessary, destroyed.

Exposure to biological hazards may occur for any pharmacy staff in contact with patients or the public or through contaminants found in the ventilation system, water or food. Controls include controlled access to pharmacy spaces and the encouragement of pharmacy staff to be immunized against infectious diseases to which they may be exposed. Ventilation systems and water supplies should be monitored regularly for microbial growth.

Engineering Controls

In the hierarchy of controls, the highest level of control is directed at the source. From an occupational health perspective, the highest level of control may be immunization of workers who may come in direct contact with infected patients. Good engineering controls such as vaccines, proper ventilation, needleless systems, safety engineered sharps, biological safety cabinets, and effective biological waste containment also contribute to minimizing the transmission of infectious agents. Engineering controls, once designed and implemented, are not under the control of the worker, but are directed at the source of the hazard.

Administrative Controls

The next level of controls includes administrative controls. Because it is not always possible to eliminate or control the hazard at the source, administrative controls are frequently used for biological hazards in healthcare. Administrative controls focus on ensuring that the appropriate prevention steps are taken, that all proper work procedures are documented, that pharmacy staff are trained to use the proper procedures, and that their use is enforced. Administrative controls include policies and procedures that establish expectations of performance, codes of practice, staff placement, required orientation and training, work schedules, and occupational health programs in which baseline immune status is recorded and immunizations are provided. Procedural controls may include procedures that relate to detection and follow-up of infectious diseases, baseline health assessments and periodic screening of workers, hazard identification and control processes, and

Potential Biological Hazards	Summary of Major Control Strategies		
	Engineering	**Administrative**	**PPE**
Exposure to bloodborne pathogens or pathogens transmitted in body fluids or secretions to mucous membranes by contact with contaminated surfaces	Restrict access to pharmacy to authorized personnel only and require that all visitors must be escorted. Vaccines.	Safe work procedures for equipment decontamination. Compliance with all infection prevention and control practices. Immunization program. Worker education	PPE based on the risk assessment may include protective clothing, gloves, eye and face protection.
Exposure to environmental biological contaminants from ventilation systems, water or food	Maintenance of ventilation systems. Early spill clean-up. Preventive maintenance of ventilation systems and water supply systems with regular testing to ensure proper functioning. Early detection and remediation of mould	Infection prevention and control practices related to building maintenance and food preparation. Protocols for construction and renovation projects that reduce contamination. Worker education.	Use of proper PPE when cleaning contaminated environmental surfaces, including gloves, respiratory protection, and eye protection.

outbreak management procedures. All work procedures should include the consideration and control of the risk of exposure to workers.

Administrative controls related to the prevention of exposure to biological hazards include the development of infection prevention and control guidelines, including equipment decontamination and safe work procedures for building maintenance and protocols for construction and renovation projects.

Surfaces must be decontaminated after any spill of potentially infectious materials and at the end of the working day. Specific written protocols must be developed and followed for each decontamination process. Pharmacy staff must be trained in all decontamination procedures specific to their activities and should know the factors influencing the effectiveness of the treatment procedure.

Personal Protective Equipment (PPE)

Personal protective equipment such Protective apparel, including gowns and coveralls, Gloves, Shoe covers Eye protection, including face masks and goggles Respirator protection, which includesN95 respirators and powered air-purifying respirators (PAPR) should be used based on the risk assessment.

PPE is often used in conjunction with other controls (engineering and administrative) to provide additional protection to workers. The primary types of PPE are designed to protect the worker from infectious disease by breaking the chain of infection at the “portal of entry or exit” of the microorganisms. This means that all PPE is designed to reduce exposure via specific routes of transmission.

Gloves, gowns and other protective clothing reduce exposure through the dermal (skin) contact route and help contain the microorganisms to the work environment. Eye and face protection reduce exposure through mucous membrane contact. Masks worn by patients reduce exposure through droplet containment at the source, and respirators worn by health care workers reduce exposure to the respiratory system.

The choice of gloves must often balance the needs for protection and dexterity. While thicker gloves (or double gloves) may appear to provide greater

protection, it may make tasks more difficult and increase the exposure risk. In Recommendations for Canadian Health Care and Public Service Settings1 it is noted that the "Selection of the best glove for a given task should be based on a risk analysis of the type of setting, type of procedure, likelihood of exposure to blood or fluid capable of transmitting blood borne pathogens, length of use, amount of stress on the glove, presence of latex allergy, fit, comfort, cost, length of cuffs, thickness, flexibility, and elasticity."

necessary for working with all harmful substances and educating workers in the practices is vital. Safe work procedures should be designed to:

- ✓ Limit the worker's exposure time
- ✓ Reduce contact with the substance through any route of exposure to the worker
- ✓ Ensure safe disposal of substances and disposable equipment that comes into contact with harmful substances
- ✓ Ensure safe handling and decontamination of reusable equipment
- ✓ Require the use of all designated controls
- ✓ Worker education is critical for safely handling harmful substances

Chemical Agents in Healthcare

The use of chemicals is widespread in healthcare and includes chemicals such as:

- cleaning agents
- disinfecting and sterilizing agents
- laboratory chemicals
- medical gases
- anaesthetic agents
- cytotoxic drugs and pharmaceutical substances.

Effects of Chemicals

Any chemical that has the potential to cause harm is called a hazardous or dangerous chemical. Such chemicals may:

- cause health effects, for example be a respiratory sensitizer or skin irritant or sensitizer;
- be a physical hazard, for example a flammable, explosive or oxidizing chemical;
- affect the environment, if they are used, stored or disposed of incorrectly.

Routes of Exposure

Healthcare workers (and in certain cases, the unborn child) may suffer health effects when dangerous chemicals enter the body. The main routes of exposure are:

- inhalation: breathing in the chemical;
- absorption: through skin contact or a splash in the eye;
- ingestion: via contaminated food or hands; and
- inoculation: when a sharp object such as a needle punctures the skin.

The Law

The Safety, Health and Welfare at Work (Chemical Agents) Regulations and the Safety, Health and Welfare at Work (Carcinogens) Regulations require that employers must assess any work activity likely to involve a risk of exposure to chemicals, carcinogens or mutagens.

Chemical safety: Key duties of employers and employees

There are key duties for employers and employees under the relevant health and safety

Employers are required to:

- Determine which hazardous substances are present in the workplace.
- Assess the risks to employees and others from the presence of these hazardous
- substances.
- Prevent or control exposure to the hazardous substances to as low a level as is reasonably
- practicable.

- Have arrangements in place to deal with accidents, incidents and emergencies.
- Provide information, training and consultation to employees.
- Make available health surveillance to employees

Employees also have duties.

They must:

- Co-operate with their employer e.g. follow procedures.
- Make full and proper use of control measures e.g.
- using extract ventilation where provided, and report any defects.
- Report any defects in plant/ equipment immediately to the employer as appropriate.
- Report any accident or incident which may have resulted in the release of a dangerous chemical/substance into the workplace

A chemical risk assessment follows the same steps as a risk assessment for any other hazards in your workplace.

There are three basic steps:

1. Identify the hazard:
2. This involves identifying the chemicals you have in your workplace and the hazards associated with them.
3. Assess the risk:
4. This involves assessing the risk from chemicals or processes in your workplace.
5. Control the exposure:

This involves considering the various recognized control measures to eliminate or reduce the risk.

Chemical Storage

An often-neglected engineering control is the proper storage of chemicals.

Chemicals must be stored properly to reduce risks of fire and explosion, chemical reactions, and worker exposure. Chemical storage must consider local fire regulations

that specify the types and quantities of specific chemicals that may be stored. Organizations should reduce the risks related to chemical storage by ensuring that only quantities of chemicals and sizes of containers that are necessary for the tasks are purchased and stored.

The temptation to save money by purchasing large quantities should be discouraged, as these quantities have more stringent storage requirements and are often more difficult (and expensive) to dispose of than to purchase.

Some major reasons why chemicals are stored improperly include:

- An initial decision (when the area is designed) to purchase small quantities of chemicals that is later reversed for economic reasons, leading to the purchase of larger quantities that exceed the storage capabilities of the area
- Lack of space to accommodate storage facilities
- "Shared" storage facilities, with no one designated as responsible for ensuring proper storage
- Confusion as to how to store chemicals that have more than one hazard • Lack of training/knowledge of chemical composition and reactivities • Bad habits related to convenience
- Lack of a well thought out chemical storage plan
- Some major reasons why chemicals are stored improperly include:
- An initial decision (when the area is designed) to purchase small quantities of chemicals that is later reversed for economic reasons, leading to the purchase of larger quantities that exceed the storage capabilities of the area
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- Bad habits related to convenience
- Lack of a well thought out chemical storage plan

How can chemicals be hazardous to health?

Chemicals can cause many different types of harm, ranging from mild skin irritation to cancer. The effects of hazardous chemicals may be seen:

- Immediately after contact (e.g. chemical burn) or many years after the exposure (e.g. lung cancer following exposure to asbestos).
- Following a single short exposure (e.g. infrequent use of a chemical) or longer-term exposures (e.g. daily use of a chemical in the workplace).Therefore, it is important to minimize exposure to chemicals at all times. In order for a chemical to be hazardous to a person's health, it must either be in contact with or enter the body.
- Effects on brain and nervous system for example, exposure to pesticides, mercury, lead, solvents, carbon monoxide gas
- Eye, nose and throat irritation (dryness, soreness or pain) For example, exposure to acid mists and vapours, welding fumes or diesel exhaust
- Effects on the lung damage. For example, asbestos (lung cancer), welding fume (chronic obstructive pulmonary disease). Irritant induced asthma. For example, acids ("burn effect" on airways). Allergic asthma (For example flour dust, isocyanate (in 2-pack paints), wood dust
- Liver damage (For example, exposure to vinyl chloride.)
- Bladder damage (For example, exposure to some azo dyes (bladder cancer)
- Effects on skin Allergic contact dermatitis (For example nickel, latex, chromate (found in some cements).
- Irritant contact dermatitis (For example solvents, detergents, oils, lubricants.
- Effects on blood and bone marrow (For example, exposure to benzene in petrol fumes (anemia and leukemia).

You have seen how chemicals effect the body. There are four ways chemicals can enter the body:

- ✓ **Inhalation:** Breathing in contaminated air is the most common way that workplace chemicals enter the body.
- ✓ **Contact with the skin or eyes:** Some chemicals can damage the skin or eyes (e.g. irritation) or pass through the skin into the body.
- ✓ **Ingestion**: Workplace chemicals may be swallowed accidentally if food or hands are contaminated. Injection: Injection can occur when a sharp object (e.g. needle) punctures the skin and injects a chemical directly into the bloodstream.

Term	What this means to you
Hazard	A hazard is anything that has the potential to cause harm, in terms of injury, ill-health or damage to the environment. For example, working with dangerous chemicals or processes which give rise to dusts or fumes.
Risk	Risk is the chance (e.g. high, medium or low) that a person or the environment will be harmed by the hazard. It also considers how severe the harm or ill-health could be.
Likelihood	Likelihood is a measure of how likely it is that an accident or ill-health could happen. When people are working and managing their chemicals safely there is less chance that an accident or ill-health will occur.
Severity / Consequence	Severity is a measure of how serious the injury, ill-health or damage to the environment could be as a consequence of unsafe working with chemicals.
Control measure	Control measures are the steps you are going to take to remove chemical hazards or at least reduce exposure to a low level.
Safety data sheet (SDS)	A safety data sheet (SDS) is a document that must be provided to you with all hazardous chemicals. It provides useful information on the chemical hazards, advice on safe handling, use and storage, and the emergency measures to be followed in case of an accident.
Label	All chemicals should be supplied with a label on the container which clearly identifies the chemical and its hazards.
CAS number	This is a unique identifying number which is assigned to each chemical. Where you encounter more than one chemical or trade name for the same chemical, you can use this number to definitively identify the chemical.
Occupational exposure limit value (OELV)	This is a concentration of a chemical in workplace air to which most people can be exposed without experiencing harmful effects.
Chemical inventory	This is a list of all the chemicals you have in your workplace.

Term	What this means to you
Acute toxicity	An adverse health effect following a single exposure to a chemical (e.g. skin contact with insecticides, accidental ingestion of a chemical).
Carcinogen	A chemical that causes or can potentially cause cancer (e.g. breathing in asbestos fibres, skin contact with used motor oils).
Chronic toxicity	An adverse health effect following repeated exposure to a chemical, which can occur following a relatively short exposure (e.g. weeks) or longer term exposure (e.g. years).
CMR	A chemical that is Carcinogenic, Mutagenic or Toxic to Reproduction.
Corrosive	A chemical that causes irreversible damage to skin, eyes or airways (e.g. strong acids and strong bases such as concentrated hydrochloric acid or concentrated hydroxides).
Irritant	A chemical that causes reversible damage to skin, eyes or airways (e.g. detergents or soaps).
Mutagen	A chemical that can cause permanent damage to genetic material in cells, which can possibly lead to heritable genetic damage or cancer (e.g. UV rays from the sun, benzene).

Work-related psychosocial hazards are on the verge of surpassing many other occupational hazards in their contribution to ill-health, injury, disability, direct and indirect costs, and impact on business and national productivity. The risks associated with exposure to psychosocial hazards at work are compounded by the increasing background prevalence of mental health disorders in the working-age population. The extensive and cumulative impacts of these exposures represent an alarming public health problem that merits immediate, increased attention.

Exposure to work-related psychosocial hazards is projected to become a major occupational health and safety threat, with significant implications for workers, businesses, and the national economy. This threat may affect many of the 169.6 million US workers by 2030 and result in adverse mental and physical health, leading to increased morbidity, mortality, and disability. In turn, these effects could have major impacts on national, business, and worker economic circumstances. Beyond their effects on health, psychosocial hazards can impair workers' ability to participate effectively in the work environment and with other people in and outside of work.

One of the defining characteristics of psychosocial hazards is their interface with the very core of work, including how work is designed and operationalized through management and human resource practices. This means the reach of the hazard can be long with tentacle-like influence on many aspects of organizations via the nature of work demands, the behaviors of workers and managers, and through organizational systems and policies. It is important to recognize that psychosocial hazards are fundamental to OHS because they are fundamental to human health. They can occur in any workplace, regardless of industry, size, equipment or tasks, simply because organizations are comprised of humans. Accordingly, psychosocial hazards should be treated as a fundamental element of OHS, rather than an add-on element.

It is somewhat difficult to consider psychosocial hazards without a concomitant focus on mental health; however, it would be erroneous to believe that these workplace hazards are relevant only to mental health. In fact, physical health outcomes, such as cardiovascular and musculoskeletal disorders1 were among the first to be recognized by

researchers and these still loom large in terms of recognized health outcomes from exposure to psychosocial hazards. As well as physical and mental health outcomes, psychosocial hazards can have a negative impact on worker health behaviours (such as unhealthy eating, low physical activity, and drug and alcohol consumption), and on organizational outcomes (such as engagement, absenteeism, turnover and performance; It has also been recognised that psychosocial hazards can delay recovery from injury/illness and therefore can influence return-to-work outcomes (Goorts et al., 2020). These widespread effects reinforce how fundamental psychosocial hazards are to OHS practice and that they cannot be treated as an add-on

Psychosocial hazards are any hazards or risks in one's environment and society that can cause harm. In a workplace setting, psychosocial hazards are things that can cause stress, which can then affect a person physically, psychologically, or both.

Difference Between Psychosocial and Psychological Hazards

In terms of workplace hazards, psychological safety and psychosocial safety are separate concerns. However, managing psychological safety can help greatly with managing psychological safety and hazards as well.

By definition, anything "psychosocial" refers to the relationships between humans with their thoughts, behaviors, and social environment. It is a term that refers to how mental health, or psychological factors, work with social factors and how they can affect a person. On the other hand, the term "psychological" refers to things, feelings, and experiences that relate to the human mind and mental health.

Following this, it can be said then that psychological factors are an aspect of one's psychosocial state, and managing it can be very beneficial.

1. Psychosocial hazards

Broadly, the term 'psychosocial' refers to the interrelationships between an individual's thoughts and behaviors, and their social environment. In literature outside the OHS field, this term often refers to social environments such as family of origin, socioeconomic status and level of education. Whilst it is important to be aware of

individual and non-work psychosocial factors, in the OHS context psychosocial hazards have come to refer only to hazards created by work and the work environment.

Established psychosocial hazards include:

- Time pressure/role overload
- Emotional demands associated with job
- Low job control
- Poorly defined roles
- Low recognition and reward.
- Poorly managed change
- Interpersonal or team conflict (including bullying, violence, and aggression)
- Organizational injustice
- Low co-worker or supervisor support
- Environmental

Psychosocial aspects of work and related hazards.

Psychosocial aspects of work	Associated psychosocial hazards
Job content	Lack of variety or short work cycles; fragmented or meaningless work; under-use of skills; high uncertainty; continuous exposure to difficult clients, patients, pupils, etc.
Workload and work pace	Work overload or too little work, machine pacing, high levels of time pressure, continually subject to tight deadlines
Work schedule	Shift work, night shifts, inflexible work schedules, unpredictable hours, long or unsociable hours
Control	Low participation in decision-making; lack of control over workload, pacing, shift working, etc.
Environment and equipment	Inadequate equipment availability, suitability, or maintenance; poor environmental conditions such as lack of space, poor lighting, excessive noise

Organizational culture and function	Poor communication; low levels of support for problem solving and personal development; poor managerial support; lack of definition of, or agreement on, organizational objectives
Interpersonal relationships at work	Social or physical isolation, poor relationships with superiors, interpersonal conflict, lack of social support, harassment, bullying, poor leadership style, third-party violence
Role in organization	Role ambiguity, role conflict, responsibility for people
Career development	Career stagnation and uncertainty, under-promotion or over-promotion, poor pay, job insecurity, low social value of work
Home-work interface	Conflicting demands of work and home, low support at home, problems relating to both partners being in the labor force (dual career)

2. Occupational stress

Having a clear understanding of the definition of occupational stress is important as the psychological and physiological stress response is the mechanism by which psychosocial hazards have an effect on people's health and wellbeing. The definition of 'stress' has been the subject of much academic and public debate. Although the term has been expected to support an immense breadth of meaning (and resultant research variability), it is now possible to draw the divergent threads together to outline the key defining characteristics of occupational stress, which stem from the evolution of stress theory.

The American Psychological Association's Dictionary of Psychology defines Occupational Stress as "a physiological and psychological response to events or conditions in the workplace that is detrimental to health and well-being".

Such responses do vary from individual to individual, and it depends on several factors such as the level of autonomy, responsibility and independence that the individual has in his or her workplace, the amount, pace and type of work that needs to

be performed, the level of safety and security associated to the work and finally the relationships that the individual maintains with his or her colleagues and supervisors.

Specifically, occupational stress can be defined as: The physiological and psychological responses of workers who perceive that their work demands exceed their resources (e.g. skills, time, support) and/or abilities to cope with the work

There are three main points to consider in relation to this definition.

- The stress response is a multi-factorial (i.e. physiological, cognitive and emotional) response to a set of stimuli that can lead to ill health.
- Stress is not a disease in its own right, but a pathway that can lead to ill-health, whether mental or physical health outcomes. The ill-health pathway occurs when there is significant 'imbalance' between the demands placed on a person, and the resources they have to cope with those demands.
- The individual's perception of their work characteristics (including their perceptions of their coping skills and how important it is to them that they cope) is an integral part of the stress equation.

Occupational stress may manifest itself in one or more of the following three different ways:

- **physical strain**—affecting the various parts of the body and this is the most common way by which occupational stress manifests itself. It can range from having mild headaches or body pain to severe migraines;
- **psychological strain**—affecting the rationale thinking abilities of an individual and can lead to loss in memory and concentration or depression and anxiety;
- **behavioral strain**—causing a change in the usual or normal habits of an individual, like, for example, binge eating or starving, excessive or loss of sleep, ignoring to perform regular tasks or duties and avoiding responsibilities and absenteeism.

There are a few theories in the field of psychology to explain the occurrence of occupational stress (Figure 3). The first and most accepted theory is the demand-control

model wherein stress can happen when the workload is high; however, the decision-making authority is low. Alternatively, when the workload is high and there is a significant lack of resources or support to perform that job, that can also lead to stress and in that case, the demand-resource model would be applicable.

Stress can occur when the skills, abilities and attitude of the employee do not match the requirements of the job, and this is called the person–environment fit model. When the efforts put in for a particular job are not rewarded appropriately in the form of pay or fair treatment or even a mere appreciation, it can lead to stress, and in this case, it is referred to as the effort–reward imbalance model.

Figure 3.

Models to explain the occurrence of occupational stress.

Cause of occupational stress

One may argue that the causes of occupational stress may not be solely due to the workplace conditions and that there are possibilities of personal factors stemming from an individual's family or social life that could have an impact on their physical and mental wellbeing. However, scientific evidences do show that several workplace conditions contribute to occupational stress in a significant manner. The various causes of occupational stress are depicted in Figure 4.

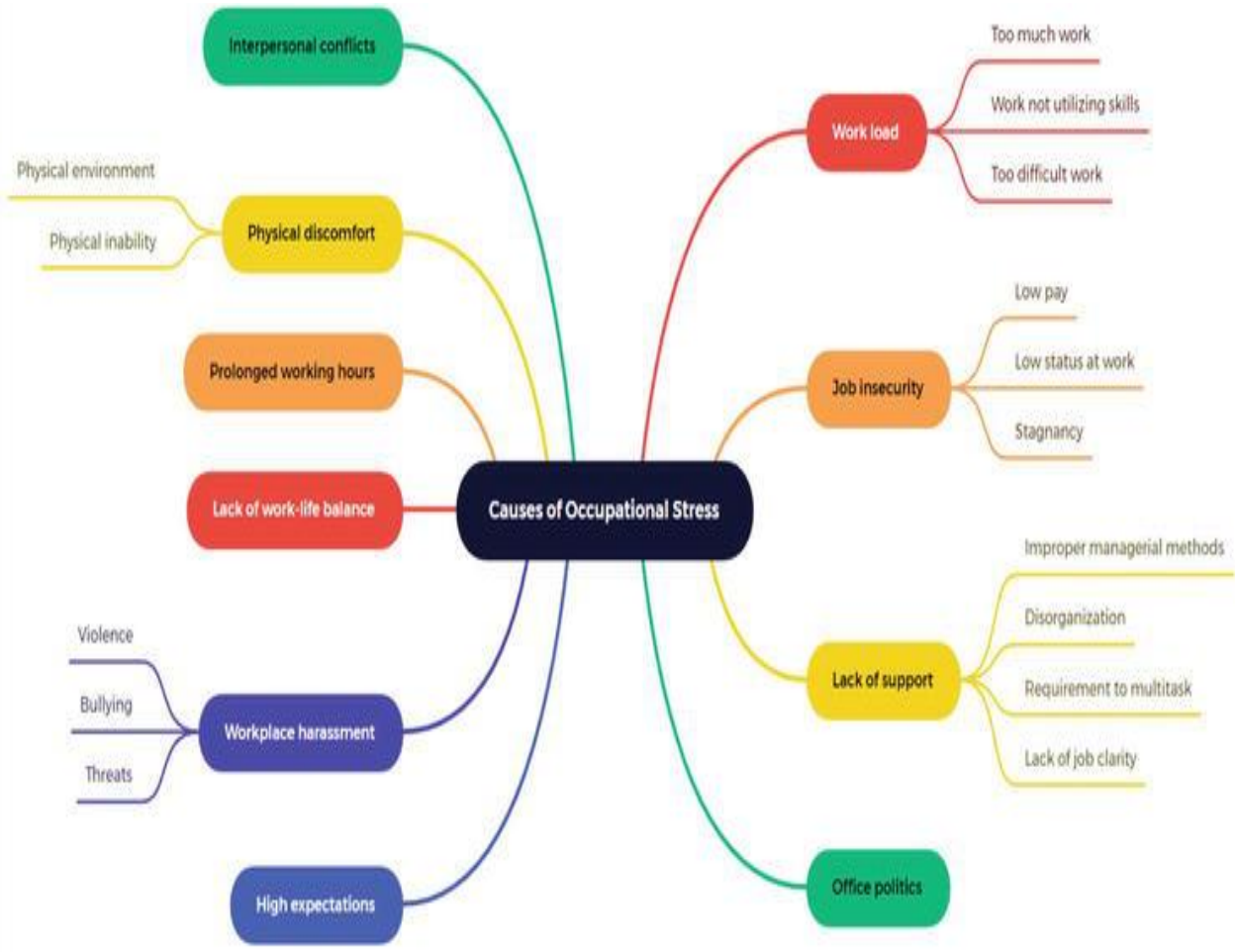


Figure 4. Causes of occupational stress.

Coping strategies

In order to manage stress, it is essential to change ones own cognitive and behavioral efforts in dealing with the external or internal stimuli that is causing the stress and this is referred to as coping. Coping strategies can be worked out at both organizational level and also at personal levels. When it comes to organizational levels, it is first important for the management to understand the causative factors in the organization and come up with suitable measures.

NIOSH recommends the following strategies for organizations to help their employees cope with occupational stress:

- Managers should keep monitoring the workload of sub-ordinates and see to it that the workers are allocated work that is well within their skills set and capabilities and can also be reasonably completed within the time frame given;

- Each job must come with a clear description of its scope of work and roles and responsibilities;
- Sufficient resources should be available for the employees to complete the tasks;
- If new tasks are to be performed, especially with advancements in technology require employees to do tasks that may be beyond their current capabilities, then, suitable training should be given to them before they can undertake those specific tasks;
- Communication channels must be transparent, and all employees should be given an opportunity to voice out their opinions and decisions;
- Different leadership styles can be explored to figure out which style works well for the organization and its employees.

On personal front, there are a few coping strategies that an individual can explore to overcome occupational stress.

First among them is seeking social support—irrespective of what the social support can provide, be it in terms of advice or suitable contacts or material help or just a distraction, getting in touch with a human contact is valued when one is undergoing stress Seeking social support is also said to help an individual to overcome exhaustion and work–family conflicts

The next strategy is the "problem-solving" strategy, wherein the individual can put up a fight against the stressor, and this goes beyond just identifying the stressor. Studies have also shown that the problem-solving strategy helps an individual to gain more control over the job and thus overcome occupational stress.

The last strategy is the "avoidance" strategy which is equated to running away from the stressor and is a form of escapism. Even though studies have shown a positive correlation between avoidance and emotional exhaustion, certain longitudinal studies indicate that avoidance can potentially lead to depression 10 years down the road or more chronic and acute conditions 4 years later.

All kinds of work require some amount of physical and mental effort and hence when done over a long period of time can lead to stress. Mental wellbeing is being spoken about all over the world, and several leaders across the globe are coming up with strategies such as four-day workweek or remote working to reduce the amount of time that an individual spends at work and ensure that he or she is able to attain work–life balance. However, it is usually not the amount of time spent at workplace that is the stressor, but what happens during the work time, irrespective of whether it is at home (while working remotely) or at office is what matters.

For example, it is almost impossible for an individual to forget a berating that he or she received during the day from his or her boss even after returning home and may even have a disturbed sleep due to that. Studies on burnout indicate that all the biggest sources of occupational stress come from an individual's boss—unreasonable timelines, lack of support, heavy workload, unfair treatment and unclear communication.

Hence, managers have to realize that with the mental wellbeing of their workers comes an increase in productivity and profit; hence, they must lend a listening ear to their issues at the workplace and try to sort things out so that it becomes a win-win situation for both parties. When coping strategies are implemented from both fronts, that is, from the management and from the employee, it would be much easier to get relieved from occupational stress.

LECTURE 6. REQUIREMENTS FOR THE LOCATION AND COMPOSITION OF PHARMACY PREMISES.

Pharmaceutical facilities are made up of a series of rooms called cleanrooms which are used for production and quality control etc. Cleanrooms typically classified as per their usage or zone and are confirmed by the measurement of particles in air. In pharmaceutical industry cleanrooms maintenance is based on the guidelines of EU GMP or by ISO14644.

The cleanliness of the air is controlled by various method like Heating, Ventilation and Air Conditioning (HVAC system)

The purpose of cleanrooms is to minimize and to create contamination free environment.

There are many sources of contamination inside manufacturing area like airborne particle, dust particles, microorganism, gases, condensates, fumes, heats spray etc. Cleanrooms must be kept clean and free from all types of contamination In Pharmaceutical manufacturing cleaning disinfectant is an important part of maintaining environmental control. These programs require the selection and usage of appropriate disinfectants, application, and validation.

Good Manufacturing Practices form part of a pharmaceutical quality system. It aims to minimize the risks in manufacture to ensure safety, quality and efficacyA manufacturer has responsibility to ensure the pharmaceutical products are fit for use, comply with marketing authorization requirements and have adequate safety, quality and efficacy. Senior management has the responsibility to ensure that the pharmaceutical quality system is adequately resourced, roles, responsibilities and authorities are clearly defined and communicated.

Pharmaceutical manufacture requires high levels of sanitation and hygiene at every point of the process, covering personnel, premises, equipment, materials, containers, and cleaning and disinfection products.

It also requires elimination of potential sources of contamination, both for hygiene purposes and for medical effectiveness, which could be affected by, for example, dust from other product ingredients or cleaning compounds

Regulatory requirements

EU regulations require all pharmaceutical manufacturers to comply with EU Good Manufacturing Practices (GMPs) if they want to supply products to the EU.

- Manufacturers and importers must be authorized and registered by a competent authority from a member state.

- ❑ Manufacturers and importers are regularly inspected by an EU competent authority or other approved authority to check compliance with the EU GMPs. This applies wherever the manufacturer is located.

In the US, the regulatory standard for human pharmaceutical products is the Current Good Manufacturing Practice regulations, which are enforced by the FDA.

- ❑ The FDA inspects manufacturers worldwide for compliance with CGMP.
- ❑ The FDA issues guidance for manufacturers in the Code of Federal Regulations, Current Good Manufacturing Practice for Finished Pharmaceuticals.
- ❑ These guidance documents do not bind companies to follow them and an alternative approach is acceptable if it fulfils the requirements of the regulations.

Sanitation and hygiene GMPs

- ➢ Good Manufacturing Practices form part of a pharmaceutical quality system. It aims to minimize the risks in manufacture to ensure safety, quality and efficacy.
- ➢ A manufacturer has responsibility to ensure the pharmaceutical products are fit for use, comply with marketing authorization requirements and have adequate safety, quality and efficacy.
- ➢ Senior management has the responsibility to ensure that the pharmaceutical quality system is adequately resourced, roles, responsibilities and authorities are clearly defined and communicated.
- ➢ Pharmaceutical manufacture requires high levels of sanitation and hygiene at every point of the process, covering personnel, premises, equipment, materials, containers, and cleaning and disinfection products.
- ➢ It also requires elimination of potential sources of contamination, both for hygiene purposes and for medical effectiveness, which could be affected by, for example, dust from other product ingredients or cleaning compounds.

Personnel requirements

- ❑ Health checks: personnel should undergo health checks before and during employment.

- Hygiene practices: all personnel involved in the manufacturing process should practice a high level of personal hygiene.
- Illness: staff having an illness or open wounds that could affect product quality must not handle starting materials, packaging, in-process materials or medicines, until they have recovered and are no longer a risk.
- Handling goods: there should be no direct contact between hands and starting materials, primary packaging materials, and intermediate or bulk products.
- Clothing: persons in the production areas should wear clean body coverings as appropriate, including production staff, contractors, employees, visitors, managers and inspectors.
- Personal habits: eating, drinking, smoking should not be allowed in the production, laboratory and storage areas.
- Food, drink, smoking products and personal medicines should not be allowed in these areas also.

Premises

- Location: premises should be located in an environment that minimizes the risk of contamination of materials and products.
- Design and layout: the design and layout of the premises must facilitate good sanitation and allow effective cleaning and maintenance to prevent cross-contamination and build-up of dirt.
- Pest control: there should be pest control procedures that encompass Integrated Pest Management (IPM) to reduce or eliminate pests.
- Cross-contamination: measures should be taken to prevent cross-contamination from dust generated during manufacturing operations from handling of ingredients.
- Cleaning: premises should be cleaned and disinfected according to written procedures and records kept.
- Services: lighting, temperature, humidity, ventilation and electrical supply should not adversely affect pharmaceutical products or the functioning of equipment.

Cleaning and Disinfection of in Pharmaceuticals

- Sanitization- Cleaning and sanitation of cleanroom and equipment are essential to prevent contamination of product and needs to be done in compliance with Good Manufacturing Practice (GMP) regulatory requirements. Cleanrooms

must be regularly cleaned and disinfected. In normal practices using a detergent, followed by the using a disinfectant in practices. It is also necessary to remove residue of the disinfectant using Purified water / Sterile water.

- In cleaning rooms, cleaning equipment and mops etc. should be of an appropriate design for the grade of cleanroom. It is ideally to use lint free mopes and wipes which ensure lowest level of particle generation during usage and cleaning. During cleaning process, a strict cleaning system should be followed.
- Cleaning and disinfection using cloths and mops is used by saturating the cleaning item and wiping the area using a series of parallel, overlapping strokes.

It is also recommended to use only one disinfectant or detergent in one go to avoid over- concentration or chemical relativities. Cleaning and disinfection should begin from cleanest area first to dirtiest area last. This helps to reduction of contaminates during cleaning process. Pharmaceutical must decide the frequency of cleaning by establishing through risk assessment process as per GMP practices.

Equipment

Layout and design: the layout and design of equipment should allow effective cleaning and maintenance and prevent cross-contamination and build-up of dirt or dust. Layout and design should not permit pest harborage.

Cleaning: equipment should be cleaned using validated procedures, according to a suitable schedule and records kept of the procedures, times and results of tests.

Equipment for cleaning: equipment for washing, cleaning and drying should be suitable for use and not contaminate products.

Premises should be suitably located, designed, constructed and maintained to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of medical products.

There should be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness. Sufficient security should be provided, and access should be controlled. Receiving and dispatch bays should be separate and should protect products from weather conditions.

Appropriate controls and segregation should be provided for products requiring specific handling or storage conditions such as radioactive materials, products containing hazardous substances and products to be stored under controlled temperature and relative humidity conditions.

Pharmacy employees must strictly comply with the rules of operation, safety an d industrial hygiene when working in pharmacies

The Rules provide for measures aimed at preventing hazards associated with the peculiarities of work in a pharmacy, namely:

- poisoning, allergic reactions, burns and other injuries caused by the use of toxic, aggressive, flammable and other substances
- Injuries during work with special devices, apparatus, equipment, glassware, etc;
- nervous overstrain;
- infection of personnel from pharmacy customers.

The premises and equipment requirements of a retail pharmacy business

"Premises" in relation to a retail pharmacy business means a fixed premise that has been registered in the retail pharmacy businesses' register and includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored.

A pharmacy owner or pharmacist must not carry on a retail pharmacy business from unregistered premises.

The name and certificate of registration of the registered pharmacist as well as the certificate of registration of the retail pharmacy business must be conspicuously displayed at the premises in which the business is carried on.

Sketch plan / Floor plan

In application for registration or continued registration of a retail pharmacy business, a sketch plan must be submitted to the PSI, setting out all those areas where medicinal products are, or intended to be, sold or supplied, prepared, dispensed, compounded or stored at the registered premises. It is not permissible to use any other area for these purposes, other than the specific areas that constitute the registered premises

External premises requirements

Structure and external appearance

- The pharmacy premises must be easily identifiable as a healthcare facility and must reflect the professional nature of pharmacy
- Public entrances to the pharmacy must be clear and accessible at all times. Pathways to the front of the premises must be safe, well maintained and level.
- All areas of the external pharmacy premises and façade, including all windows, sills, doors, and roofs must be of sound construction, intact, in a good state of repair and decoration.
- Fascia, guttering and paintwork must be kept clean and in good order and surfaces must be non-shedding. Both the external and internal premises must be free from leaks and exposed wiring.
- Effective pest control measures should be adapted to prevent entry of rodents and other pests.

- Any signage used on the exterior of the pharmacy must be clear,legible and not misleading. Notices informing the public of arrangements for accessing pharmacy services such as opening hours, duty rotations, after hour's services, etc. should be present, prominently displayed, factual and up-to-date.
- Window displays must be professional in nature, free from dust, clutter and insects and be appropriate to that of a healthcare facility.
- Posters on windows and doors should be kept to a minimum, be professional in character and facilitate sufficient visibility to ensure security is not compromised.
- Illuminated exterior signs should be in good repair and in working order. The pharmacy title/trading name must be clearly displayed near public entrances.

Internal premises requirements

General guidance applies to all relevant areas within the pharmacy, including the dispensary, the patient consultation area and the public areas of the pharmacy including all areas where professional pharmacy services are accessed.

- Patients entering the pharmacy should be readily able to identify where they can access the pharmacist and where prescriptions are dispensed. Appropriate signage (e.g. Advice and Consultation Area / Prescriptions) must be displayed and the prescription reception area kept free of clutter.
- The layout and fittings in respect of the storage of medicinal products must facilitate their appropriate storage and supervision of their sale or supply by the pharmacist. A mechanism should be in place whereby the patient is made aware

that there is ready access to a pharmacist. Adequate heating, lighting and ventilation/air conditioning should be provided to ensure the correct storage and safe dispensing of medicinal products within the pharmacy.

- A suitable waiting area with seating option should be provided for patients, giving consideration to the privacy of others. Pharmacies are required to provide a separate, designated, conveniently located patient consultation area within the pharmacy which, at a minimum, allows for a private discussion between the pharmacist and patient and/or their carer about matters related to their medicine therapy or general health. All pharmacy fixtures, fittings and décor (including all storage areas) must be fit for purpose, of sound construction and compliant with all health, safety and environmental requirements. The finish of all fixtures, fittings and décor must be professional, complete, well maintained and free of any damp and mound.

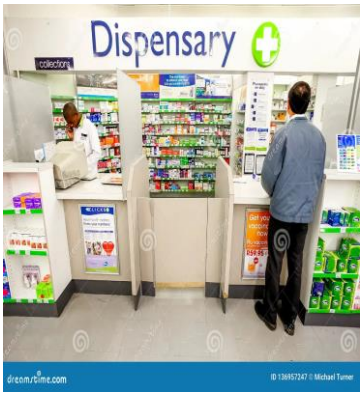
- All walls, ceiling, plaster and paintwork must be safe, non-shedding, cleanable, and clean and in keeping with that expected from a health care facility.
- All floors within the registered premises should be undamaged, intact and with an even surface. Flooring should be of a cleanable material and should be clean.

  Carpets are not recommended.

- Spillages should be dealt with directly and appropriate safety notices must

  be used to identify wet or slippery floors. In so far as is practical, aisles must be clear of obstacles
- All areas of the pharmacy should be kept clean and a written and regular cleaning schedule and sign off sheet should be in place for all areas of the pharmacy,

including the dispensary and all staff/public/storage areas and such records maintained for inspection upon request



Dispensary

The dispensary should be suitably sited within the premises so as to allow all patients ease of access to dispensing services. Medicinal products that are subject to prescription, including prescription veterinary products, as well as controlled drugs must not be accessible to the public for self-selection, and should therefore be stored in the dispensary. A designated and adequate space must be provided in the dispensary for the storage of prescription veterinary medicines. Public entry into the dispensary itself must be restricted, with appropriate surveillance and barriers in place and such entry should be prohibited except for persons authorized for a specific purpose.

The boundary between the dispensary and the non-prescription medicines/other professional services area should be appropriate in design, ensuring that the supervision of the sale and supply of all medicinal products and other professional activity is facilitated, while also maintaining adequate security and confidentiality of the dispensary activity

Space and Layout

The environment within which a pharmacist carries out their professional role in particular within the dispensary, should support high quality patient care.

The dispensary size and layout, including the surface area of the dispensary bench, must reflect and be sufficient for the volume of prescriptions dispensed and take practice-specific variables such as service provision and staffing levels into account.

The dispensary size and layout must facilitate an uninterrupted, safe and efficient workflow and permit effective and direct supervision by the pharmacist of, and effective communication between, all staff involved in the preparing, compounding or dispensing of medicinal products.

The dispensary should be organized to keep distractions to a minimum and provide for the safe delivery of patient care.

Sufficient space must be available for the safe and effective storage of all dispensary medicines and medicines should be stored at an accessible shelf height i.e. pharmacy staff should not have to reach excessively to access them

Fixtures and Fittings

All fixtures and fittings within the dispensary must be fully finished to a high standard and in good condition, suitable and adequate for the purpose for which they were intended. Appropriate shelving and fixtures must be in place so that no medicinal products are stored on the floor, on stairs, in passageways or in toilets.

- The dispensing bench and all working surfaces must be clean, cleanable, uncluttered and impervious to dirt and moisture. All working surfaces should be smooth and have a minimal number of joints which must be sealed to prevent entry of moisture or liquids.
- Specific work areas should be identified and appropriately maintained for the purpose of extemporaneous preparation and for monitored dosage services
- The dispensary should be well-lit and sufficiently ventilated and must be maintained hygienically and be free from all sources of contamination.
- The dispensary must have arrangements for the proper storage and disposal of all types of waste materials. A clean sink of impervious nature and surround and with a plumbed waste pipe must be present in the dispensing area. The sink should be used for professional activity only and both hot and cold water must be available. A source of drinking (potable) water should also be present in the dispensary
- The use of televisions or radios and/or other broadcast telecommunications devices or media should be appropriate to a healthcare facility and should not be a source of distraction within the dispensing area.

Storage areas within the registered premises

Storage areas within there All storage areas and facilities within the registered premises, including fixtures and fittings, walls, ceiling and paintwork must be in keeping with that expected from a health care facility and maintained to a high standard. Storage areas should be self-contained. Sufficient storage space should be allocated to allow the orderly management of stock and effective stock rotation glistered premises. The pharmacist must be able to effectively control all medicinal products and confidential records within the pharmacy, including all areas accessible to employees, and no unauthorized access must be permitted. Control and supervision must be demonstrable with appropriate security and stock control policies and procedures in place.

Staff areas

Adequate staff facilities should be available, including a separate area for staff to prepare and eat food. Eating must not be permitted in the dispensing area. Adequate heating and lighting should be provided in all employee areas

All staff areas, including fixtures and fittings, walls, ceiling and paintwork should be in keeping with that expected from a health care facility and maintained at a good standard. Entry to all staff areas and facilities, including stock rooms, toilet facilities, communal areas and administration offices must be controlled and restricted.

Provision should be made for toilet and hand-washing facilities for staff, with both hot and cold water. The toilet area should not open directly into the dispensary

and must not be used for storage. A "Now wash your hands" or similar reminder notice (professionally produced) should be displayed in the toilet area.

Policies and Procedures

- Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place for all aspects of premises requirements outlined in these guidelines and for any pharmacy-specific methods of premises maintenance.
- Cleaning and maintenance procedures should be developed and maintained for all areas of the premises.
- There should be procedures in place which outline the processes involved in maintaining effective security, including security assessments, on-going security audits and appropriate training of personnel.
- The arrangements and layout of the premises must enable personal supervision to be exercised by a registered pharmacist of any preparation, dispensing or compounding and of the sale or supply of medicinal products, including veterinary medicinal products, at one and the same time and a policy must be in place which ensures this.
- There should be a specific policy ensuring reasonable accommodation is made for patients and employees with disability, ensuring the equal access requirements under the Equal Status Acts are fulfilled.
- Every pharmacy should have documented procedures and policies in place to facilitate compliance with all relevant Building and Fire Regulations as well as Health and Safety legislation.

PPE (Personal Protective Equipment

The employer and the superintendent pharmacist must inform all pharmacy staff about any risks and tasks that require the wearing of protective equipment for example, the compounding of specific extemporaneous preparations or the handling of cytotoxic medication.

Protective equipment must be provided depending on the service being provided (such as protective clothing, eyewear, and gloves).

Only employees who have received appropriate training and have reached the required level of proficiency should operate pharmacy equipment and carry out the tasks within a particular procedure. Employees also have a duty to take reasonable care for their own safety and to use any protective equipment supplied.

LECTURE 7. OCCUPATIONAL HEALTH AND SAFETY WHEN WORKING WITH HAZARDOUS MEDICINES.

Hazardous Drugs

OSHA says worker exposure to hazardous drugs is a major health concern for workers in healthcare facilities and the pharmaceutical industry. The preparation, administration, manufacturing, and disposal of hazardous medications are the primary activities that may expose hundreds of thousands of workers to potentially significant workplace levels of these chemicals.

Health Effects

Hazardous drugs can cause serious acute and chronic health effects such as skin rashes, fertility problems, genetic damage, birth defects, organ toxicity, and possibly leukemia and other cancers.

Potentially harmful exposure can occur when you handle or work around hazardous drugs. These drugs include antineoplastic cytotoxic medications, anesthetics, anti-viral drugs, hormones, and others.

Antineoplastic Drugs

The numbers and types of work environments, including pharmacies that contain antineoplastic drugs are expanding as these agents are used increasingly for nonmalignant rheumatologic and immunologic diseases and for chemotherapy in veterinary medicine. The likelihood that a worker will experience adverse effects from antineoplastic and other hazardous drugs increases with the amount and frequency of exposure and the lack of proper work practices. The following case

illustrates one example of the health effects reported after exposure to antineoplastic drugs.

Hazardous Drug Exposure

Exposure occurs during manufacturing and packaging, receiving, preparation and administration, and cleaning and disposal activities. Clinical and non-clinical workers with potential exposure include:

- pharmacists and pharmacy technician's nurses
- physician assistants ·
- physicians
- nursing home, home health care, and assistive care staff
- housekeeping and environmental services staff (custodial, laundry, and waste handling workers)
- shipping and receiving personnel
- veterinarians and veterinary technicians and assistants

Exposure Routes

Exposures to hazardous drugs may occur through inhalation, absorption, ingestion, or injection. The most common route of entry for chemical substances is through inhalation (i.e., breathing). Absorption through the skin, unintentional ingestion from hand-to-mouth contact, and unintentional injection by needle sticks or sharps are also possible.

Hazard Communication Standard

Employers should implement a written program which meets the requirements of the Hazard Communication Standard (HCS) for employees who are handling or exposed to the chemicals, including drugs that represent a health hazard to employees. Manufacturers are responsible for evaluating their chemical products, and creating the Safety Data Sheet (SDS), which is the most comprehensive written information about that chemical.

The written program must provide for worker training, warning labels, and access to Safety Data Sheets (SDSs). HCS Labeling and SDS best practices include the following actions:

- Always check container labels before starting any task involving a chemical.

- Labels placed on containers are basic and typically do not include pertinent, detailed information so in some instances refer to the Safety Data Sheet or SDS.
- Any chemical transferred from its original container to a secondary container must be labeled with at least the basic information from the original container.

Hazardous Drug Safety and Health Plan

As part of the HCS, a written Hazardous Drug Safety and Health Plan should also be developed. It should be readily available and accessible to all employees, including temporary employees, contractors, and trainees.

OSHA says the plan should include each of the following elements and indicate specific measures that the employer is taking to ensure employee protection:

- Standard operating procedures relevant to safety and health considerations to be followed when health care workers are exposed to hazardous drugs.
- Criteria the employer uses to determine and implement control measures to reduce employee exposure to hazardous drugs, including engineering controls, the use of personal protective equipment, and hygiene practices.
- A requirement that ventilation systems and other protective equipment function properly, and specific measures to ensure proper and adequate performance of such equipment.
- The plan should have a provision for information and training and medical examinations of potentially exposed personnel.
- The circumstances under which the use of specific hazardous drugs require prior approval from the employer before implementation.
- Employers should designate a responsible person to implement the Hazardous Drug Safety and Health Plan. This includes assigning a Hazardous Drug Officer (who is an industrial hygienist, nurse, or pharmacist health and safety representative) and, if appropriate, establishment of a Hazardous Drug Committee or a joint Hazardous Drug Committee/Chemical Committee.

HCS Information and Training

HCS information and training are a critical part of the hazard communication program. It is through effective information and training that employees will learn to read and understand labels and SDSs, determine how to acquire and use them in the pharmacy, and understand the risks of exposure to the chemical as well as the ways to protect themselves.

According to the Hazard Communication Standard (HCS), the employer must provide information and training to each pharmacy employee who may be "exposed" to hazardous chemicals. "Exposure" or "being exposed" means that an employee has contacted a hazardous chemical at work through any route of entry and is subject to its affects. Employees must be trained on how to safely handle hazardous chemicals to which they may be exposed prior to initial assignment and whenever the chemical hazard changes. Topics for HCS training include:

- the requirements of the HCS;
- any operations in their work area where hazardous chemicals are present;
- the location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and SDSs required by the HCS.

Employer Responsibilities

Departments with employees who handle hazardous drugs on a regular basis must:

- Ensure employees follow the procedures in the hazardous drug safety and health plan. ·
- Develop additional written procedures as appropriate.
- Ensure all hazardous drugs are labeled properly and safety data sheets are available for all drugs in liquid, powdered, and gaseous form.
- Develop a plan for cleaning up hazardous drug spills and provide spill kits to all areas where hazardous drugs are administered. Whenever possible, spills of

liquid hazardous drugs will be handled by employees in the area of the spill.

Employee Responsibilities

- Employees who handle hazardous drugs should:
- Comply with the procedures outlined in the plan and with department- or site-specific procedures related to handling hazardous drugs.
- Report any exposures (skin or eye contact or inhalation of an aerosol or dust) to their supervisors.

Hazard Assessment

The hazard assessment is conducted to help you identify what tasks have the potential for exposure, which employees may be exposed, and how to control exposure. It will form the foundation of your Hazardous Drug Control Program.

Written Hazard Assessment

Here are some steps to help you conduct your hazard assessment:

- Develop an inventory of hazardous drugs stored, transported, or otherwise handled in your facility.
- Identify the tasks performed where an employee may be reasonably anticipated to have exposure to a hazardous drug.
- Characterize the potential exposure for each task, including exposure by contact, injection, or inhalation.
- Determine the preventive methods that will be used for each of the identified tasks and exposures for your work operations and worksites.
- Complete a diagram of the physical layout of your work areas where hazardous drugs may be located or used; however, a diagram will not be needed for temporary worksites.

HCS Exemptions

OSHA requires SDSs only for materials that meet OSHA's definition of "hazardous," and are "known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency".

Drugs regulated by the U.S. Food and Drug Administration (FDA) are covered by the HCS. However, section (b)(6)(vii) of the HCS exempts FDA drugs when they are:

- in solid, final form for direct administration to the patient (e.g., tablets or pills) drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs)
- drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)
- Examples of those needing SDS's for drugs would include pill manufacturing facilities and pharmacies (if the drug is compounded, crushed etc.).

There are other exceptions to the standard, such as:

- Drugs dispensed by a pharmacy to a health care provider for direct administration to a patient (e.g., tablets or pills).
- OSHA considers most office products (such as pens, pencils, adhesive tape) to be exempt under the provisions of the rule, either as articles or as consumer products.
- "Articles" such as paper clips, pencils, office equipment, and furniture, etc.
- Food and food products which are sold, used, or prepared in commercial
- establishments, and foods intended for personal consumption.
- Cosmetics packaged for sale to consumers, or intended for personal consumption by employees.
- Tobacco and tobacco products.
- Wood or wood products, including lumber when the only hazard they pose is the potential for flammability or combustibility.
- Biological hazards are exempt under the HCS if the only hazard they pose is biological. Examples include microbes, vaccines, and cell cultures.

Hazardous Drug Training

All personnel who are involved an ANY aspect of the handling of hazardous

drugs, such as physicians, nurses, pharmacists, housekeepers, and employees involved in receiving, transporting, or storing) must receive information and training to protect them in the work area.

The training should include methods of observation to detect the presence or release of an HCS-covered hazardous drug. For example, the monitoring conducted by the employer, continuous monitoring devices, or the visual appearance or odor.

The training should also include these components:

- physical and health hazards of the covered hazardous drugs in the work area
- measures employees can take to protect themselves from these hazards (including specific procedures the employer has implemented to protect employees from exposure)
- appropriate work practices
- emergency procedures for spills or employee exposure

Recommended Good Work Practice Procedures

There are other necessary work practice procedures to protect workers against hazardous drugs. For example, nursing stations on floors where hazardous drugs will be administered should have spill and emergency skin and eye decontamination kits available and relevant MSDSs for guidance.

Also, a list of drugs covered by hazardous drug policies and information on spill and emergency contact procedures should be posted or easily available to employees.

Biological Safety Cabinets

Approved Biological Safety Cabinets (BSC) should be used when preparing hazardous medications.

- Class II, type B, or Class III BSCs that vent to the outside are recommended.
- OSHA does not recommend Horizontal BSCs for the preparation of hazardous drugs, since they increase the likelihood of drug exposure.

The BSC should also contain:

- covered needle containers for needle disposal
- covered waste container for excess fluids disposal

Decontamination

Decontamination of a BSC must consist of surface cleaning with water and detergent, followed by a thorough rinsing. Spray cleaners should be avoided because of the risk of spraying the HEPA filter. Ordinary decontamination procedures which include fumigation with a germicidal agent, are inappropriate in a BSC because such procedures don't remove or deactivate the hazardous drugs.

Removable work trays should be lifted in the back of the BSC to be cleaned. During cleaning, the worker should wear appropriate personal protective equipment (PPE) similar to those used for spills. The exhaust fan/blower should be left on and cleaning should proceed from least to most contaminated areas. The drain spillage trough area should be cleaned at least twice since it can be heavily contaminated.

Hazardous Drugs During Preparation

Employees can be exposed to hazardous drugs during preparation because of ineffective engineering, or work practice controls, or personal protective equipment (PPE).

The outside of bags or bottles containing the prepared drug should be wiped with moist gauze. Entry ports should be wiped with moist alcohol pads and capped. Transport should occur in sealed plastic bags and in containers designed to avoid breakage. Shipped hazardous drugs that are subject to Environmental Protection Agency regulation as hazardous waste, are also subject to Department of Transportation regulations.

Non-liquid HD's: The handling of non-liquid forms of hazardous drugs requires special precautions as well. Tablets which may produce dust or potential exposure to the handler should be counted in a BSC. Capsules, such as gel-caps or coated tablets, are unlikely to produce dust unless broken in handling. These are counted in a BSC on equipment designated for hazardous drugs only, because even

manual counting devices may be covered with dust from the drugs handled. Automated counting machines should not be used unless an enclosed process isolates the hazard from the employee(s).

Personal Protective Equipment

OSHA requires the use of effective PPE when working with hazardous drugs. Here are some examples:

Gloves

The thickness of the gloves used in handling hazardous drugs is more important than the type of material. The best results have been seen with latex gloves.

Double gloving is recommended because all gloves are permeable to some extent, and their permeability increases with time.

- When double gloving, one glove should be placed under the gown cuff and one over. The glove-gown interface should be such that no skin on the arm or wrist is exposed.
- To limit transfer of contamination from the BSC into the work area, the outer gloves should be removed after each task or batch, and should be placed in "zipper" closure plastic bags or other sealable containers for disposal.
- Gloves should be changed hourly or immediately if they are torn, punctured, or contaminated with a spill.
- Thicker, longer, latex gloves that cover the gown cuff are recommended with minimal or no powder since the powder may absorb contamination.
- Hands should be washed before gloves are put on and after they are removed.

Gowns

A protective disposable gown must be made of lint-free, low-permeability fabric with a closed front, long sleeves, and elastic or knit closed cuff should be worn.

Respiratory Protection

A NIOSH-approved respirator appropriate for the hazard must be worn to afford protection until a BSC is installed. The use of respirators must comply with OSHA's Respiratory Protection Standard 105. The standard outlines the aspects of a

respirator program, including selection, fit testing, and worker training.

Surgical masks are not appropriate since they do not prevent aerosol inhalation. Permanent respirator use, in lieu of BSC's, is imprudent practice and should not be a substitute for engineering controls.

Eye and Face Protection

Whenever splashes, sprays, or aerosols of HD's may be generated that can result in eye, nose, or mouth contamination, chemical-barrier face and eye protection must be provided and used in accordance with 29 CFR 1910.133. Eyeglasses with temporary side shields are inadequate protection.

When a respirator is used to provide temporary protection as described above, and splashes, sprays, or aerosols are possible, employee protection should be:

- respirator with a full face piece
- plastic face shield or splash goggles complying with ANSI standards2 when using a respirator of less than full-face piece design. Eyewash facilities should also be made available.

Restricted Preparation Areas

OSHA and the American Society of Hospital Pharmacists recommend hazardous drug preparation should be performed in a restricted area. This area should have visible signs to restrict the access of unauthorized personnel.

- Bins or shelves where hazardous drugs are stored should be designed to prevent breakage and to limit contamination in the event of leakage, with bins with barrier fronts, or other design features that reduce the chance of drug containers falling to the floor.
- Warning labels should be applied to all hazardous drug containers, shelves, and bins, where these containers are stored.

The American Society of Hospital Pharmacists (ASHP) recommends hazardous drugs requiring refrigeration be stored separately from non-hazardous drugs in individual bins designed to prevent breakage and contain leakage.

Restricted Activities

Smoking, drinking, applying cosmetics, or eating where hazardous drugs are prepared, stored, or use increases the chance of exposure, and should be prohibited.

Handling Practices

Workers can be exposed to hazardous drugs through improper handling practices, needle or sharps handling and disposal, and priming IV lines or labeling.

When handling these hazardous drugs, good work practice should be in place. The hazardous drugs should be prepared by pharmacists, not nurses or physicians without proper PPE and engineering controls. The risk of exposure to hazardous drugs through inhalation or direct skin contact, is present in procedures such as:

- transferring hazardous drugs from one container to another, reconstituting or manipulating them
- withdrawal of needles from drug vials
- expulsion of air from a drug-filled syringe

Sharps Handling

OSHA and the American Society of Hospital Pharmacists (ASHP) recommend all syringes and needles used in the course of preparation be placed in "sharps" containers for disposal without being crushed, clipped or capped.

Priming of Tubing for Hazardous Drugs

OSHA recommends drug administration sets be attached and primed within the BSC prior to addition of the drug. This eliminates the need to prime the set in a less well-controlled environment. The priming should be done with non-drug containing solution or a back-flow closed system should be used.

Labeling Practices

In addition to standard pharmacy labeling practices, all syringes and IV bags containing hazardous drugs should be labeled with a warning label such as, “Special Handling/Disposal Precautions.”

Hazardous Drugs During Administration

Workers can be exposed to hazardous drugs during administration; therefore, personnel should wear gowns, latex drugs, and chemical splash goggles or equivalent safety glasses.

When administering aerosolized drugs, additional precautions may be necessary to protect employees from exposure such as:

- wearing NIOSH-approved respirators
- using treatment booths with local exhaust ventilation systems, or isolation rooms with separate HEPA filtered ventilation systems

The American Society of Hospital Pharmacists (ASHP) recommends these guidelines when administering hazardous drugs:

- Only those trained to administer hazardous drugs should be allowed to perform this function.
- Disposable gloves and gowns should be worn. The glove and gown cuffs should be worn in a manner that produces a tight fit (e.g., loose glove tucked under gown cuff; tight glove fitted over gown cuff).
- Intravenous containers designed with venting tubes should not be used.
- The use of plastic backed absorbent liners under I.V. tubing during administration of hazardous drugs to absorb any leakage and prevent the solution from spilling onto patient skin.
- Work at waist level, if possible; avoid working above the head or reaching up for connections or ports.
- Until the reproductive risks associated with handling hazardous drugs have been substantiated, staff who are pregnant or breast-feeding should avoid contact with these drugs.

Disposal of Hazardous Drugs

OSHA requires bags containing materials contaminated with hazardous drugs be covered under the Hazard Communication Standard and must be properly labeled

Thick, leak-proof plastic bags, colored differently from other hospital trash

bags, should be used for routine collection of discarded gloves, gowns and other disposable material, and labeled as “Hazardous Drug-related wastes.” The waste bag should be kept inside a covered waste container cleared labeled “Hazardous Drug WASTE ONLY.” At least one such receptacle should be located in every area where the drugs are prepared or administered. Waste should not be moved from one area to another. The bag should be sealed when filled and the covered waste container taped.

Hazardous drug-related wastes should be disposed of according to EPA, state and local regulations for hazardous waste. This disposal can occur at either an incinerator or a licensed sanitary landfill for toxic wastes, as appropriate. Commercial waste disposal is performed by a licensed company. While awaiting removal, the waste should be held in a secure area in covered, labeled drums with plastic liners.

LECTURE8. SAFETY AND PERSONAL HYGIENE OF PERSONNEL WHEN WORKING IN PHARMACIES

Proper hygiene is essential in the pharmaceutical industry to prevent contamination and ensure the quality of medicinal products. In the pharmaceutical industry, hygiene holds the utmost importance to ensure the safety of both end consumers and employees. There are four key areas to focus on: production hygiene, personnel hygiene, plant and surface disinfection, and performance monitoring

1.Performance monitoring

Production hygiene requires a controlled environment

Production hygiene is the first step in making the process and end-product safe.

Following these practices will help to maintain optimal sanitation standards in pharmaceutical production plants and ensure that the quality of the drugs remains unaffected:

- Focus on a controlled environment: a cleanroom maintains a low level of airborne microbes, dust, chemical vapours, and aerosol particles.
- Implement the use of classical, sterile, or microbial filtered disinfectants in addition to the manual disinfection process.
- Streamline the disinfection process with a hydrogen peroxide vapor generator. These powerful machines are becoming more popular, as they provide fast and effective decontamination of the manufacturing unit and equipment.
- Ensure all cleaning equipment meets the requirements of optimal ergonomics, sterilization, and cleanroom processes.
- Check the premises carefully to identify hard-to-clean surfaces, and clean these areas with disinfectants that are lab-tested for efficacy and compliant with industry safety standards.
- Cement the storage areas and walkways to minimize the risk of spreading impurities.
- The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

2. Personnel hygiene begins with choosing the right clothes.

Despite the measures taken to maintain hygiene for production facilities, equipment, raw materials, and product packaging, one of the primary sources of contamination is human beings. Using appropriate and hygienic work wear is crucial to maintaining high standards of safety and ultimately ensuring the wellbeing of end consumers:

1. Implement the use of hygienic specialised garments in specified work areas such as production facilities, storage areas and loading and unloading units.

2. The garments prevent contamination from particles generated by, and microorganisms shed from, the body;

- Gowns are sterilized and non-shedding, and cover the skin and hair (e.g., caps, snoods for mustaches and beards, protective goggles);
- All overlapping gown components have an adequate barrier between them (e.g., gloves overlapping sleeves). Make sure there's the right kind of hygienic specialised garments available in sufficient numbers at all times so that all personnel accessing the aseptic manufacturing are appropriately gowned. Pay special attention to ensure that:
- Gloves are sanitized frequently and torn or defective gown components are changed immediately

3. Provide education and training on the importance of hygiene and the proper way to use hygienic clothing (e.g., not using the clothing when away from the manufacturing environment or using the canteen, smoking area, and toilets).

- Focus on the laundry process: it should be done only by an approved contractor or an in-house facility conforming to industry-defined criteria that validate the entire process. The following measures must be taken to ensure the highest standards of hygiene in work wear laundering:
- Clean the work wear effectively and in compliance with industry standards.
- Make sure dirty and clean work wear are appropriately separated.
- Provide clean clothing in contamination-free bags or covers.
- Verify and validate the laundry process and improve it continuously.

3. Facility and surface disinfection helps fight contamination

In addition to practicing effective production and personnel hygiene, proper measures should also be taken to disinfect the facility and all surfaces.

1. Use high-quality, industry-approved sterilization products that are tested for efficacy, user-friendliness, and occupational safety.

2. Ensure the walls, ceilings and floors are washable and have no crevices; regular cleaning, scrubbing & disinfection are important to avoid impurity accumulation and the spread of contaminants.

3. Implement the use of high-performance hand disinfectants and dispensing systems to meet the highest standards of hand hygiene – one of the most critical preventive measures to avert the risk of germ & impurity transmission by the hands of the personnel.

Performance monitoring is smooth and easy with digital tools

Merely implementing hygiene strategies is not enough; it's equally important to monitor the effect of the measures taken, analyse the process and improve continuously. With the help of digital tools, this can be done effectively and quickly.

- Identify problem areas and take necessary measures to eliminate the bottlenecks and improve the processes.
- Monitor hygiene performance with digital tools that give you an up-to-date view of the entire manufacturing, storage, work wear, and cleaning process.
- Utilize data to make sure the processes run smoothly and to avoid bottlenecks in the process.

Standard Precautions

The pharmacist must follow the general standards of pharmacy infection control in the hand hygiene and PPE. These are the '…minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered"

Its components are as follows:

- Hand hygiene (hand wash or, hand rub)
- PPE usage (viz. gloves, masks, eyewear).
- Respiratory hygiene / cough etiquette
- Sharps safety through engineering along with control of work practice.
- Safe injection practices (i.e., applying aseptic technique for parenteral medications)
- Use of sterile instruments and devices
- Environmental surfaces-cleaning and disinfection.

Hand hygiene

1. Each pharmacy staff should perform daily checks about the availability soap and alcohol-based hand rub in their work area and rest room

2. Decontaminate hands with alcohol-based hand rub (preferentially) or soap and water (especially, when visibly soiled with blood and body fluid) in the following situations

3. Before and after handling medications equipment,

4. Before and after direct patient contact,

5. Before and after handling the medication,

6. Before and after of clean and sterile procedures,

7. Before donning sterile gloves or after removing the gloves,

8. Before and after handling medical devices. For instance, respiratory devices, and intravascular catheters (palpating, replacing, accessing, repairing, or dressing)

9. Before eating and after using a restroom,

10. After contact with blood, body fluids, mucous membranes, non-intractable skin, and wound dressings (here hand washing is indicated),

11. After contact with inanimate objects in the patients' immediate environment,

12. If moving from a contaminated body site to a clean body site

Hand Hygiene techniques

1. Each section of pharmacy department should contain a hand wash station and hand rub dispenser, such as a hand sanitizer (Isopropyl Alcohol 75%).

2. The pharmacists should wash before starting any work and after finishing based on above situations

3. The pharmacist should be the hand according to procedures (Figure 1) by soap and water.

4. Use the water and soap before beginning the work or each activity as mentioned above and at any location of the pharmaceutical sections such as an outpatient pharmacy, inpatient pharmacy, community pharmacy, repackage area, drug

information section, clinical pharmacy section, medications safety officer, pharmacy infection unit, and pharmacy research section

5. Use water and soap plus hand sanitizer for any pharmaceutical compounding (sterile or non-sterile)

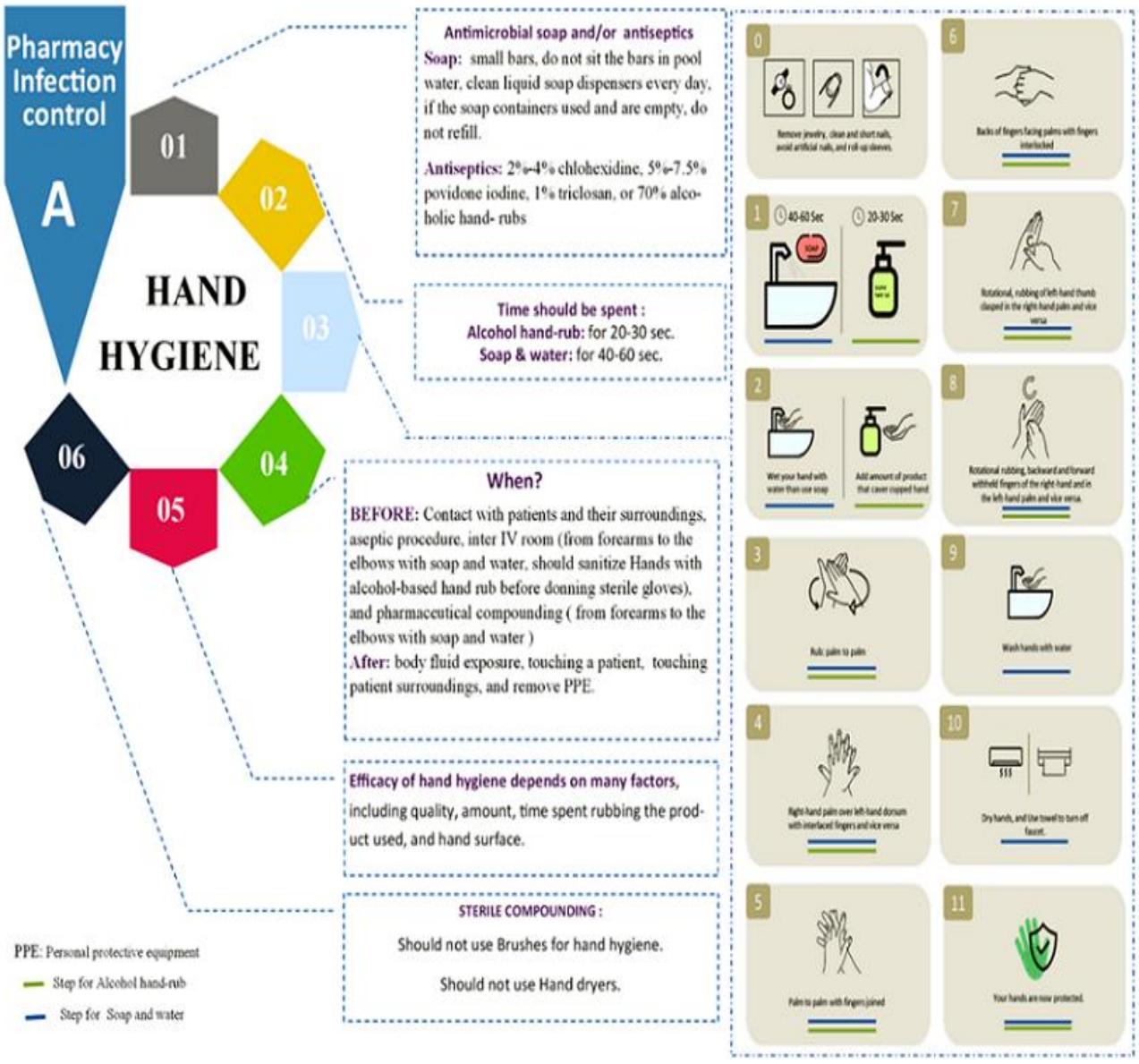


Fig.5 Principle of Personal Protective Equipment (PPE) Procedures

Skin care

1. The pharmacy workers might use the hand lotions or creams to reduce the irritant effect of hand sanitizer and antiseptics.

2. Follow the manufacture recommendations about the lotions or creams and related effects on soaps that is being used at healthcare organization.

Personal Protective Equipment (PPE)

1. There are several types of equipment the pharmacist should use in practice, Gown mask or respirator, glass or face shield, and gloves (Figure 2).
2. The pharmacist should don the PPE in proper sequence after hand hygiene with soap and water or alcohol-based hand rub.
3. All personal items and jewelries like watches, rings, bracelets, should be removed
4. The pharmacist should finish drinking or eating food and toilet before using PPE
5. The pharmacist should check all PPE material for manufacturing defect.
6. To wear the gown with the seal in the back first below the head and middle of the back.
7. The surgical mask or respirator should wear as secondary with a seal in the top back of the head and back crown of the head.
8. The glasses or face shield should wear.
9. The gloves should wear the right hand then left hand.
10. Once the pharmacist finish work, all PPE should remove at the same place before going to another site (Figure 3).
11. First, the pharmacist should remove gloves of the left hand, then the right hand without touching the gloves after removing.
12. The Gown should be removed by opening the two sealed and pending the Gown. Use gowns without touching the inside or opposite face of Gown. Throw the disposable Gown was used in
13. The glasses face mask should remove at the third one and disposable in the wastage back
14. The face mask or respirator should be removed by one side and another side without touching it and thrown in the basket

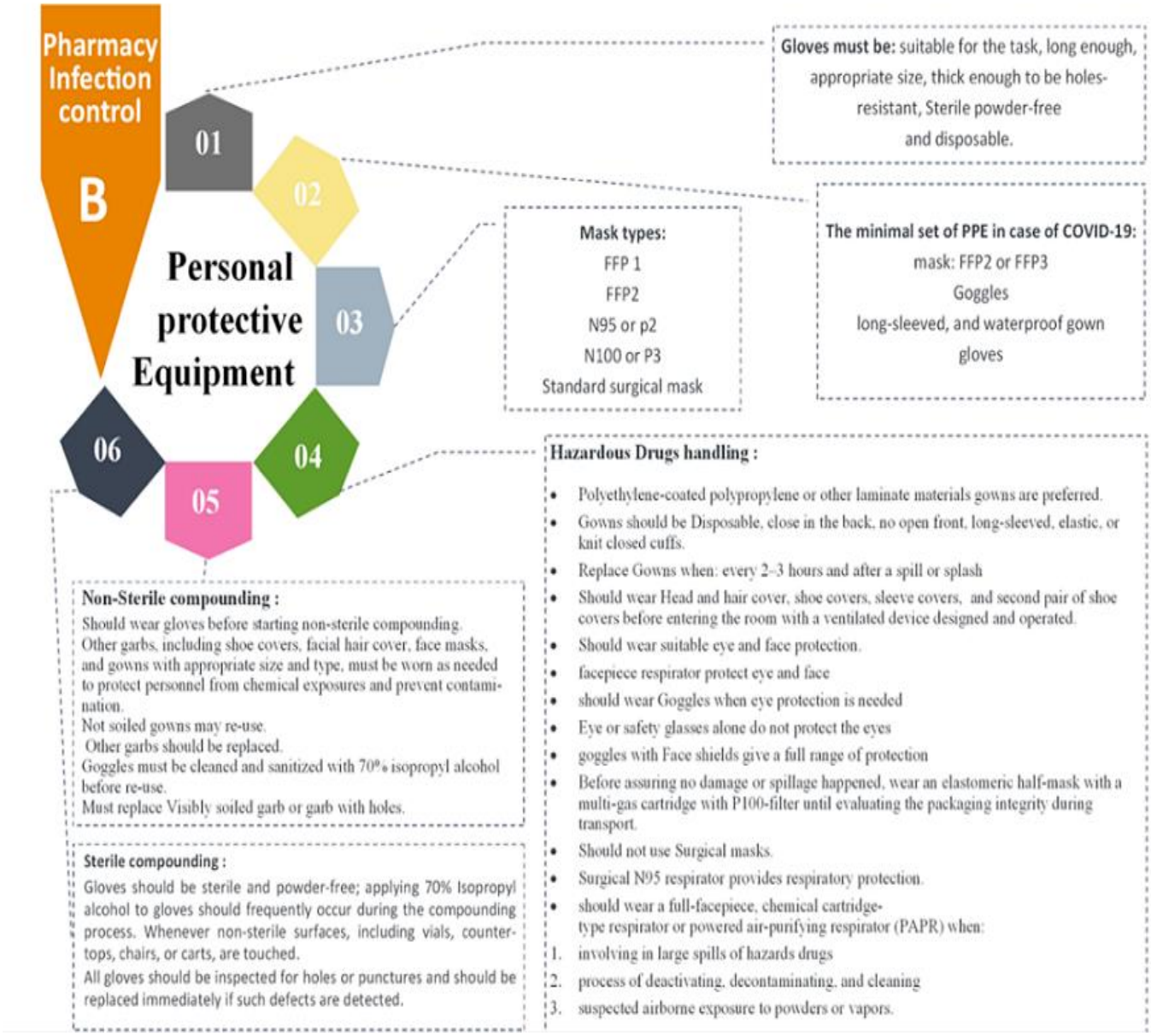


Figure 6: Principle of Personal Protective Equipment on and off techniques

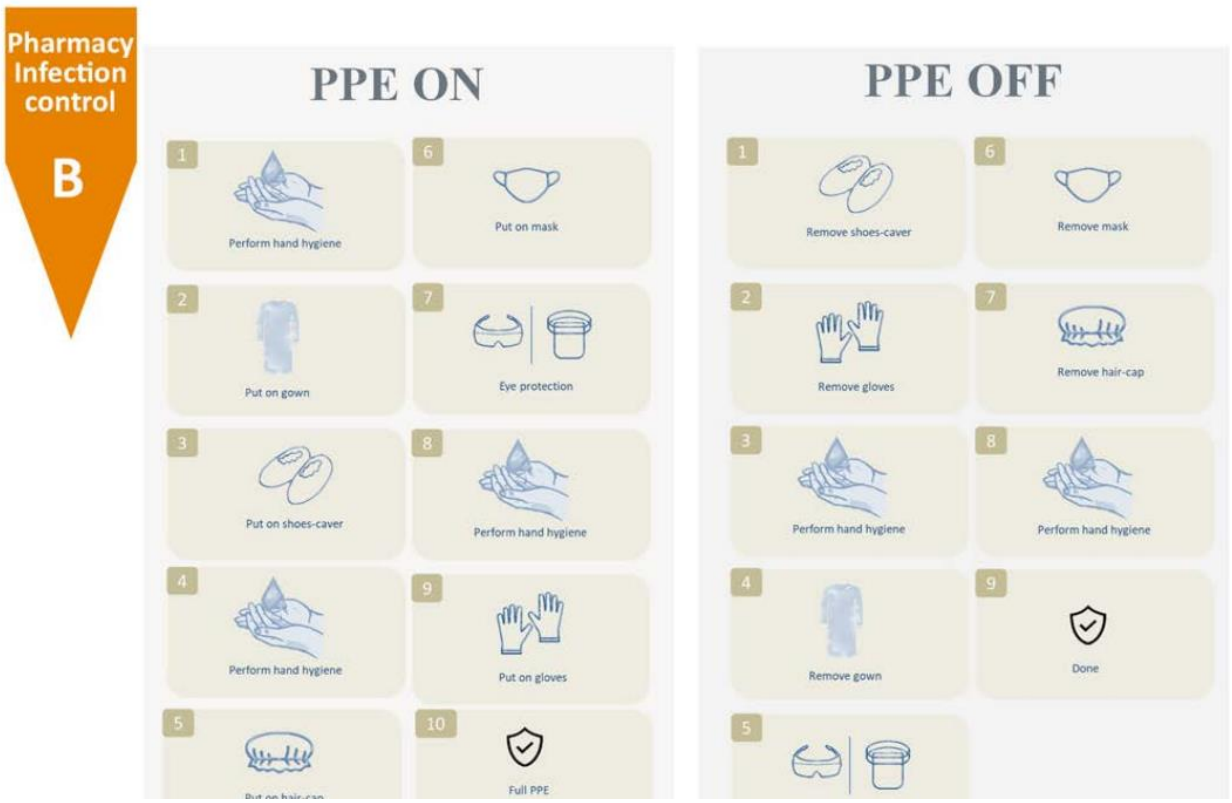


Figure 7. Principle of Personal Protective Equipment on and off techniques

Other hand hygiene requirements

1. Do not wear artificial fingernails or extenders when preparing the medication or have direct contact with high-risk patients such as in intensive care patients or those with chronic diseases such as diabetes mellitus.

2. Keep tips of natural nails as small as possible.

3. Do not wear the same pair of gloves if you go out from preparation area, and do not wash gloves between uses with different pharmacy preparation areas or patients.

4. Change gloves during pharmaceutical products if moving from a contaminated pharmacy site to a clean site.

5. Monitor pharmacy worker's compliance with recommended hand hygiene practices.

6. Provide pharmacy workers education and training about the hand hygiene and PPE and related activities for each type of patient to prevent transmission of microorganisms.

7. Provide hand-hygiene material for all pharmacy staff.

8. Investigate the outcome of following hand hygiene on pharmaceutical products and patients.

Hand-hygiene agents

1. Choose the most appropriate formulations for hand-hygiene products in pharmacy practice.

2. Evaluate the safety and efficacy of infection control products and materials.

3. Assess the advantages and disadvantages of hand sanitizer and antiseptics.

4. Choose a suitable device to encourage the usage and optimal application of hand-hygiene agents.

5. Choose the suitable hand lotions or creams to minimize the potential irritation associated with hand-hygiene agents

Cleaning requirements for the pharmacy

Pharmacies play a crucial role in our healthcare system, providing essential medications and healthcare products to patients. To maintain the integrity of these life-saving substances and ensure the safety of both customers and staff, pharmacies have specific and stringent cleaning requirements that go beyond typical commercial cleaning standards.

Infection Control

Pharmacies handle medications that are administered to patients, including those with compromised immune systems. Contamination of these medications can lead to serious health risks. Therefore, pharmacies must adhere to rigorous infection control measures.

Cleanroom Standards

Some pharmacies, especially compounding pharmacies, operate cleanrooms. Cleanrooms are highly controlled environments with low levels of airborne particles, microbes, and other contaminants. Maintaining these conditions is essential to prevent contamination of sterile medications.

Surface Disinfection

Pharmacy countertops, workstations, and prescription-filling equipment must be regularly cleaned and disinfected to prevent cross-contamination. Alcohol-based disinfectants are often used for these surfaces.

Prescription Filling Stations

The prescription filling area is a high-risk zone for contamination. Regular cleaning of pill counting trays, spatulas, and dispensing equipment is crucial.

Storage Areas

Pharmacies must maintain clean and organized storage areas for medications. Proper temperature control, cleanliness, and labeling are vital to ensure medication safety.

Pharmacy Shelving and Racking

Dust and debris can accumulate on shelves and racks, potentially contaminating medications. These areas should be regularly cleaned and sanitized.

Floor Care

Pharmacy floors must be kept clean and free of dust and debris. Regular sweeping, mopping, and floor disinfection are essential.

Hand Hygiene Stations

Pharmacies should provide accessible hand hygiene stations for both employees and customers. These stations should be regularly maintained and stocked with hand sanitizers or soap.

Ventilation and Air Quality. Pharmacies should maintain proper ventilation to control airborne contaminants. HVAC systems should be regularly cleaned and maintained to ensure clean indoor air.

Pharmacy Compounding. For compounding pharmacies, sterile compounding areas require meticulous cleaning and adherence to USP Chapter <797> standards to prevent contamination of compounded medications.

Emergency Cleanup Protocols

Pharmacies should have emergency cleanup protocols in place for spills and accidents involving hazardous or contagious substances. These protocols must be followed to minimize risks.

Regular Audits and Inspections

Regular audits and inspections are essential to ensure compliance with cleanliness standards, including those set forth by regulatory bodies like the FDA and State Boards of Pharmacy.

Cleaning Products and Procedures for USP General Chapter <797>Compliance

The most pharmacy operations, the pharmacy staff cleans both the controlled environment and the area where drugs are stored. In hospital settings, the environmental services department may have this responsibility. Some hospital pharmacies elect to integrate the environmental-services department into weekly and monthly cleaning procedures, but perform daily cleaning themselves. Regardless of who performs the cleaning, they must be carefully trained once the cleaning protocol is established and educated in proper garbing and hand-washing. Routine observation of individuals performing cleaning and inspection of the controlled environment are recommended.

Cleaning and Sanitizing Agents

There are many choices in cleaning agents, and their expense and actions vary greatly. Though isopropyl alcohol is widely used to clean ISO Class 5 compounding surfaces, 3% hydrogen peroxide and 2% sodium hypochlorite (bleach) solutions are also effective as sanitizing agents.

1 Recent data from the CDC states that a sodium hypochlorite solution of 500 ppm is effective against almost all surface bioburden. It is suggested that the

solution be made at 1000 ppm to allow for degradation if diluted with sterile water and used as a hand disinfectant.

Cleaning procedures

- solutions must be changed every seven days with newly prepared solution, labeled with their expiry dates, and kept immediately outside the ISO Class 5 area (on a cart outside the hood or workbench) for use in re-sanitizing hands prior to reentry.
- Tap water may be used with the appropriate cleaning agent for all other surfaces including walls, ceilings, production/storage bins, cleanroom-grade-steel furniture, and exterior surfaces of the workbench or hood.

Cleaning equipment and supplies

- Buckets and other cleaning equipment, such as mop handles, heads, and covers, must be dedicated to the area where they are used. To prevent cross-contamination, equipment used to clean walls and ceilings should not be used to clean floors, nor should they be taken outside of the pharmacy area.
- Equipment used to clean an ISO Class 6 or 7 area should not be used to clean an ISO Class 8 area. Because different equipment is required for different areas, a "mop forest"—a variety of mop handles hanging on the walls, beside a myriad of buckets inverted on racks—may grow in your anteroom where space is usually at a premium. To tackle this problem, consider investing in stainless-steel handles that can be used in a variety of areas and bucket-less systems.
- Conventional mops with cellulose heads generally begin shedding after two days and should be changed at least every 48 hours. Conventional plastic mop handles also do not stand up well to cleaning and need to be replaced about once a month. Buckets must be metal free and made of heavy-duty plastic.

The persons responsible for cleaning must "garb up" and wash their hands in the same manner as com- pounding personnel.

Cleaning shouldgenerally occur from the cleanest area to the dirtiest—from an ISO Class 6 or 7 cleanroom to the ISO Class 8 anteroom. Generally, cleaning should be done from top to bottom. For example, the order for a monthly cleaning would be ceilings; walls, windows, and horizontal sur- faces; workbench

shields; ISO Class 5 surfaces; workbench or hood legs; and finally, the floor. Daily cleanings should be performed at the end of the compounding day.

ACTIVITIES IN CONTROLLED ENVIRONMENTS	DAILY	WEEKLY	MONTHLY
Empty waste receptacles and replace liners	(Or as oftenas needed)	X	X
Remove hazardous-waste receptacles	X	X	X
Remove biohazardous materials	X	X	X
Cleanse ISO class 5 workstations (including compounders residing in the workstations)	X	X	X
Clean sinks, countertops, cart tops, stool tops, and exterior of sharps containers	X	X	X
Mop floors	X	X	X
Clean windows, walls, and all other horizontalsurfaces, including doors and side, front, andback of hoods, from top to bottom		X	X
Empty, clean, and sanitize storage shelving and bins		X	X
Clean and sanitize any other non-compound-ing furniture (carts, stools, waste containers)		X	X
Clean and sanitize interior and exterior of refrigerators and incubators (not kept in con-trolled environment)			X
Clean ceilings of all controlled environments			X

ISO Class 5 workstation work surfaces (IV bar to the bench sur- face, end panels, interior walls, and compounders) should be wiped with the designated agent at the beginning of each compounding day. In the event of a drug spill, wipe the spill with sterile water, if in the ISO Class 5 area, or with tap water, using a lint-free wipe, followed by the designated cleaning agent. This process will avoid the occurrence of chemical reactions between pharmaceutical components and cleaning agents.

It is important to make certain that all surfaces are thoroughly coated and wetted with the cleaning agent. The mop must go over every surface of the cleanroom wall, molding, ceiling, return grills, doors, window, handles, etc. It is usually easiest to use lint-free cloths dampened with the cleaning agent to clean molding, door handles, and other areas that are not entirely flat. It may be necessary to keep a stainless-steel or plastic step stool in the compounding room

for the manual cleaning of hard to reach areas. It is difficult to accurately benchmark the time it takes to perform daily, weekly, and monthly cleaning since the size of the facility and the number and experience of the people performing the cleaning will differ vastly between organizations.

Generally speaking, daily cleaning of a 15-by-15- foot cleanroom and 15-by-10-foot anteroom will take between 45 and 60 minutes, weekly cleaning will take about 80 minutes, and monthly cleaning will take about two hours.

LECTURE 9. ELECTRICAL SAFETY.

Electricity can kill or severely injure people and cause damage to property. However, employers can take simple precautions when working with or near electricity and electrical equipment to significantly reduce the risk of injury to themselves, their workers and others around them.

The main causes of electrical injuries at work are:

- accidental contact with non-insulated conductive parts of electrical equipment;
- use of defective hand-held power tools;
- use of non-standard or defective portable lamps with a voltage of 220 or 127 V;
- work without reliable protective equipment and safety devices;
- touching ungrounded electrical equipment enclosures that are energized due to damaged insulation;
- non-compliance with the rules of installation, technical operation and safety rules for the operation of electrical installations, etc.

The main hazards of working with electricity are:

- electric shock and burns from contact with live parts;
- injury from exposure to arcing, fire from faulty electrical equipment or installations;
- explosion caused by unsuitable electrical apparatus or static electricity igniting flammable vapours or dusts, for example in a spray paint booth.

Electric shocks can also lead to other types of injury, for example by causing a fall from ladders or scaffolds etc.

Employers' responsibilities

They must ensure an assessment has been made of any electrical hazards, which covers:

- who could be harmed by them;
- how the level of risk has been established;
- the precautions taken to control that risk.

The risk assessment should take into consideration the type of electrical equipment used, the way in which it is used and the environment that it is used in.

Employers must make sure that the electrical installation and the electrical equipment is:

- suitable for its intended use and the conditions in which it is operated;
- only used for its intended purpose.
- In wet surroundings, unsuitable equipment can become live and make its surroundings live too. Fuses, circuit-breakers and other devices must be correctly rated for the circuit they protect. Isolators and fuse-box cases should be kept closed and, if possible, locked.
- Cables, plugs, sockets and fittings must be robust enough and adequately protected for the working environment. Employers must ensure that machinery has an accessible switch or isolator to cut off the power quickly in an emergency.

Maintenance

So far as reasonably practicable employers must make sure that electrical equipment and installations are maintained to prevent danger.

Users of electrical equipment, including portable appliances, should carry out visual checks. Employers and workers must remove the equipment from use immediately and check it, repair it or replace it if:

- the plug or connector is damaged;
- the cable has been repaired with tape, is not secure, or internal wires are visible etc.;

- burn marks or stains are present (suggesting overheating).

Repairs should only be carried out by a competent person (someone who has the necessary skills, knowledge and experience to carry out the work safely).

It is good practice if employers arrange for more frequent checks for items more likely to become damaged (e.g. portable electrical tools and equipment that is regularly moved, or used frequently or in arduous environments). Less frequent checks are needed for equipment less likely to become damaged (e.g. desktop computers etc.).

Visual checks are not usually necessary for small, battery-powered items, or for equipment that works from a mains-powered adaptor (laptops or cordless phones etc.). However, the mains-powered adaptor for such equipment should be visually checked.

Employers must consider whether electrical equipment, including portable appliances, should be more formally inspected or tested by a competent person thinking also about the intervals at which this should be done.

Arrangements should be made for inspecting and testing fixed wiring installations, i.e. the circuits from the meter and consumer unit supplying light switches, sockets, wired in equipment (e.g. cookers, hairdryers) etc., to be carried out regularly so there is little chance of deterioration leading to danger. This work must normally be carried out by a competent person, usually an electrician.

Electrical systems

All electrical systems have the potential to cause harm. Electricity can be either "static" or "dynamic." Dynamic electricity is the uniform motion of electrons through a conductor (this is known as electric current). Conductors are materials that allow the movement of electricity through it. Most metals are conductors. The human body is also a conductor. This document is about dynamic electricity.

Note: Static electricity is accumulation of charge on surfaces as a result of contact and friction with another surface. This contact/friction causes an accumulation of electrons on one surface, and a deficiency of electrons on the other surface. The OSH Answers document on How Do I Work Safely - Static Electricity has more information.

Electric current cannot exist without an unbroken path to and from the conductor. Electricity will form a "path" or "loop". When you plug in a device (e.g., a power tool), the electricity takes the easiest path from the plug-in, to the tool, and back to the power source. This is action is also known as creating or completing an electrical circuit.

Kinds of injuries result from electrical currents

People are injured when they become part of the electrical circuit. Humans are more conductive than the earth (the ground we stand on) which means if there is no other easy path, electricity will try to flow through our bodies.

There are four main types of injuries***: electrocution (fatal), electric shock, burns, and falls.*** These injuries can happen in various ways:

Direct contact with exposed energized conductors or circuit parts. When electrical current travels through our bodies, it can interfere with the normal electrical signals between the brain and our muscles (e.g., heart may stop beating properly, breathing may stop, or muscles may spasm).

When the electricity arcs (jumps, or "arcs") from an exposed energized conductor or circuit part (e.g., overhead power lines) through a gas (such as air) to a person who is grounded (that would provide an alternative route to the ground for the electrical current).

Thermal burns including burns from heat generated by an electric arc, and flame burns from materials that catch on fire from heating or ignition by electrical currents or an electric arc flash. Contact burns from being shocked can burn internal tissues while leaving only very small injuries on the outside of the skin.

Thermal burns from the heat radiated from an electric arc flash. Ultraviolet (UV) and infrared (IR) light emitted from the arc flash can also cause damage to the eyes.

An arc blast can include a potential pressure wave released from an arc flash. This wave can cause physical injuries, collapse your lungs, or create noise that can damage hearing.

Muscle contractions, or a startle reaction, can cause a person to fall from a ladder, scaffold or aerial bucket. The fall can cause serious injuries.

Self-inspection checklists by electrical safety

- Electrical work performed by workers or contractors complies with OSHA standards.
- Sufficient access and working space is provided and maintained around all electrical equipment to permit ready and safe operations and maintenance
- Workers make preliminary inspections and perform appropriate tests to determine conditions before starting work on electrical equipment or lines
- In wet or damp locations, electrical tools and equipment are appropriate for the use or location or otherwise protected

Metal measuring tapes, ropes, hand-lines and similar devices with metallic thread woven into the fabric are not used where they could come in contact with energized parts of equipment or circuit conductors

- Portable ladders with nonconductive side rails are used where the worker or the ladder could contact exposed energized parts of equipment, fixtures, or circuit conductors
- Disconnecting switches and circuit breakers are labeled to indicate their use or equipment served
- Electrical installations are approved not only for the class of location, but also for the ignitable or combustible properties of the specific gas, vapor, dust, or fiber that may be present

- Whenever a worker is exposed to contact with parts of fixed electric equipment or circuits that have been de-energized, the circuits energizing the parts are locked out or tagged, as appropriate
- Workers who regularly work on or around energized electrical equipment or lines are instructed in cardiopulmonary resuscitation (CPR)
- Workers do not work alone on energized lines or equipment over 600 volts.
- Barricades and safety signs are used to prevent or limit access to areas where workers could be exposed to uninsulated energized conductors or circuit parts
- Cord-connected, electrically operated tools and equipment are effectively grounded or of the approved double insulated type
- Flexible cord sets (extensions cords) used with grounding-type equipment have grounding conductors
- Cord-connected, electrically operated equipment, and flexible cord sets (extension cords) are visually inspected before use for external defects (e.g., loose parts, deformed and missing pins, or damage to outer jacket or insulation) and for evidence of possible internal damage (e.g., pinched or crush outer jacket)
- Exposed wiring, and cords with frayed or deteriorated insulation, are immediately removed from service
- Flexible cords are only used in continuous lengths without splice or tap.
- Multiple plug adaptors are not used.
- Electrical appliances such as vacuum cleaners, polishers, vending machines, etc. are grounded
- Non-grounding type receptacles and connectors are not used for grounding-type attachment plugs

- Ground-fault circuit interrupters are installed on each temporary 15 or 20 ampere, 120 volt alternating current (AC) circuit at locations where construction, demolition, modifications, alterations, etc., are performed
- Metal cable trays, metal raceways, and metal enclosures for conductors are grounded.
- Disconnecting means are always opened before fuses are replaced.
- Flexible cords and cables are connected to devices and fittings so that strain relief is provided to prevent pull from being directly transmitted to joints or terminal screws
- Cord, cable, and raceway connections are intact and secure.
- Energized parts of electrical circuits and equipment are guarded against accidental contact by approved cabinets or enclosures
- Unused openings (including conduit knockouts) in electrical enclosures and fittings are closed with appropriate covers, plugs, or plates
- Electrical enclosures such as switches, receptacles, junction boxes, etc., are provide with tight-fitting covers or plates
- The location of electrical power lines and cables (overhead, underground, under floor, other side of walls, etc.) is determined before digging, drilling, or similar work is begun
- Temporary circuits are protected by suitable disconnecting switches or plug connectors at the junction with permanent wiring
- Disconnecting switches for electrical motors in excess of two horsepower are able to open the circuit when the motor is stalled without exploding
- Low voltage protection is provided in the control devices of motors driving machines or equipment that could cause injury from inadvertent starting
- Motor disconnecting switches or circuit breakers are located within sight of the motor control device

- The controller for each motor that exceeds two horsepower is rated equal to, or above, the rating of the motor it serves

LECTURE10. FIRE SAFETY REQUIREMENTS IN PHARMACIES

1.Introduction to Fire Safety Practices in Pharmaceutical Industries

Pharmaceutical industries are highly regulated and the products they manufacture are often life-saving medications that require careful handling and storage. However, with the use of flammable chemicals and high-temperature processes, pharmaceutical facilities pose a significant fire risk. Fire safety practices are critical to protecting the employee and investment. This comprehensive guide will provide an overview of common fire hazards in pharmaceutical industries, fire prevention measures, and emergency response and evacuation procedures. Drug manufacturers may ensure the safety of their personnel and the integrity of their operations by employing these practices.

Common Fire Hazards in Pharmaceutical Industries

Pharmaceutical manufacturers are susceptible to fire dangers due to the presence of flammable chemicals, gases, and solvents. For example; the storage and handling of flammable liquids such as ethanol, methanol, and acetone are one of the most common fire hazards in the pharmaceutical industry.

Another common fire hazard in pharmaceutical industries is the accumulation of dust particles. Dust particles from pharmaceutical products can accumulate on surfaces and machinery, creating a potential ignition source. These particles can generate a static charge which may be one of the fire reasons.

Electrical equipment and wiring also pose a significant fire hazard in pharmaceutical industries. Overloaded circuits, damaged wires, and faulty electrical equipment can cause sparks, which can ignite flammable materials and lead to a fire.

In addition, wrong garbage disposal of waste products such as paper, cardboard, and packaging materials can create a fire hazard. These materials are flammable and may quickly cause fires, resulting in a dangerous situation.

It is essential for pharmaceutical industries to identify and address these common fire hazards to prevent accidents and protect lives and investments.

Fire Prevention Measures in Pharmaceutical Industries

Pharmaceutical companies are highly regulated, and severe fire safety practices must be followed. Fire prevention techniques are critical for ensuring employee safety, protecting investments, and preventing property damage. Here are a few useful fire protection measures that pharmaceutical companies can put in place:

Conducting regular inspections or visits to the facility can help identify potential fire hazards. This includes checking electrical wiring, equipment, and storage areas for any signs of damage or malfunction.

Proper storage of flammable materials is essential to preventing fires. These materials should be stored in a designated place away from sources of ignition and heat. They must be labeled for easy to identify.

Installing fire suppression equipment such as sprinklers, fire alarms, and extinguishers can help in the prevention of fires. It is critical to ensure that these systems are frequently maintained and tested to ensure proper operation.

Employee fire safety training can help avoid fires and minimize damage in the event of an emergency. Employees should be instructed on how to handle dangerous products, use fire extinguishers, and safely.

Implementing a strict no-smoking policy within the facility can help prevent fires caused by cigarettes or other smoking materials.

By implementing these fire prevention measures, pharmaceutical industries can significantly reduce the risk of fires and protect their employees, investments, and property.

Emergency Response and Evacuation Procedures in Pharmaceutical Industries

It is critical to have adequate emergency response and evacuation procedures in place in the case of a fire. These procedures are even more important in the pharmaceutical industry, where hazardous compounds are present.

The first step in emergency response is to sound the alarm and inform all facility workers. This can be done by an automated system or by persons who have been trained to handle such situations. Employees should right away stop all work and follow the approved evacuation procedures once the alarm has been noticed.

Evacuation routes should be clearly marked and easily accessible. Employees should be trained on the location of emergency exits and assembly points outside the building. It is also important to have designated personnel who are responsible for assisting individuals with disabilities or injuries during the evacuation process.

During an evacuation, it is essential to remain calm and follow instructions from designated personnel. Employees should not attempt to retrieve personal belongings or re-enter the building until given permission by the appropriate authorities.

After the evacuation, it is important to conduct a headcount to ensure that all personnel has safely evacuated the building. Emergency responders should be notified of any missing individuals or potential hazards that may impede their efforts.

Regular training and drills should be conducted to ensure that all employees are familiar with the emergency response and evacuation procedures. By having effective procedures in place and ensuring that all personnel is properly trained, pharmaceutical industries can protect both lives and investments in the event of a fire.

Whether it is chemical or a pharmaceutical company, industrial safety has got utmost important considering products and people.

There are number of fire incidences that happen regularly for those industries who don't follow safety practices.

Either they don't have proper knowledge or they don't give importance to safety at all. And focus on producing heavy commercial batches to meet their business needs compromising safety.

What they don't understand is their negligence may cause business as well as human loss.

Fire if not appropriately handled, may turn into a disaster. Right knowledge of fire and its mitigation is necessary to all working individuals.

Let's see some basics in fire and safety and then we'll talk about fire types and extinguishers.

Safety stands on two pillars, i.e. Risk and Hazard.

Hazard is something that can cause harm or damage to business assets or humans. For example, Chemicals, Electricity, Noise, Fire, Stress, working on height or in a confined space, etc.

Risk is the probability of any hazard actually causing the harm. The risk depends on the 'n' number of factors that can put us in danger. For example, in a gasoline storage area, an electrical spark can cause harm through fire. The likelihood of happening the actual incidence is a risk.

We can say that fire is a hazard and has risk potential if not addressed correctly.

What Is Fire? How Does It Differ From Flame?

Fire: Rapid oxidation of material because of the process of chemical combustion, liberating different energies such as light, heat, smoke, and chemicals.

Flame: Visible portion of the fire that can be seen through the naked eyes. Red-Orange flame shows incomplete combustion while Blue flame shows complete combustion.

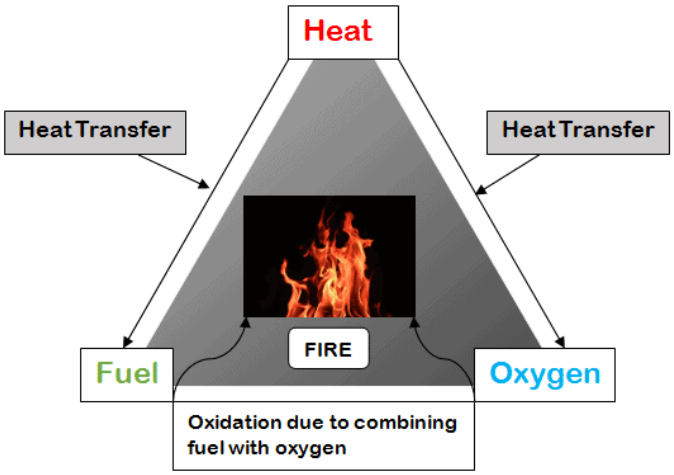
Let's first understand how the fire starts and what elements lead to fire when they come into contact.

Fire Triangle

The term 'Fire Triangle' might be familiar to you, but let's take an another look at it.

There are 3 necessary elements required to cause a fire.

- Source of Ignition (Heat)
- Fuel (Wood, Plastic, Clothes etc.)
- Oxygen



Fire Triangle and Cause of Fire

According to the above diagram:

All elements (Heat, Fuel, and Oxygen) depend on each other.

The fire can cause if and only if all elements are present at the same time.

Fire will not ignite if any one of the elements is absent.

To prevent fire, you need a tool that eliminates any one component from the fire triangle and ultimately breaks the fire triangle.

Fire Types and Extinguishers

A fire class is a system of categorizing fire with regard to the type of material and fuel for combustion. Class letters are often assigned to the different types of fire, but these differ between territories. There are separate standards for the United States, Europe, and Australia. This is used to determine the type of extinguishing agent that can be used for that fire class.

Class A fires consist of ordinary combustibles such as wood, paper, fabric, and most kinds of trash. They may be extinguished by water, wet chemical suppression, or dry chemical powder.

Class B: Flammable liquid

Class B fires are those where the fuel is flammable or combustible liquid. The US system includes flammable gases in their "Class B". In the European/Australian system, flammable liquids are designated "Class B" having flash point less than 100 °C (212 °F). These fires follow the same basic fire tetrahedron (heat, fuel, oxygen, chemical reaction) as ordinary combustible fires, except that the fuel in question is a flammable liquid such as gasoline, or gas such as natural gas. A solid stream of water should never be used to extinguish this type because it can cause the fuel to scatter, spreading the flames. The most effective way to extinguish a liquid fire is by inhibiting the chemical chain reaction of the fire, which is done by dry chemical and Halon extinguishing agents, although smothering with CO2 or, for liquids, foam is also effective. Halon has fallen out of favor in recent times (except for aircraft fire extinguishing systems) because it is an ozone-depleting material; the Montreal Protocol declares that Halon should no longer be used. Chemicals such as FM-200 are now the recommended halogenated suppressant.

Class B (US)/Class C (EU/AU): Flammable gases

Fires where the fuel is flammable or combustible gas are classified as "Class C" in the European/Australian system, and "Class B" along with flammable liquids in the US system. Due to the gaseous nature of the fuel, these

fires are difficult to extinguish. The most effective techniques for the control of a flammable gas fire are to stop the flow of fuel (by turning off any gas taps or valves) or to displace the oxygen. Control of fires involving flammable gases where the gas source cannot be controlled must be carefully managed. If the flames are extinguished, but the gas continues to leak, an explosive atmosphere may be created, and the gas may find a source for reignition outside of the originally affected area. Strategies employed to manage these fires may include trying to direct or contain the fire to prevent the ignition of other fuels whilst work is done to control the fuel supply.

Class D: Metal

Class D fires involve combustible metals - especially alkali metals like lithium and potassium, alkaline earth metals such as magnesium, and group 4 elements such as titanium and zirconium

Metal fires represent a unique hazard because people are often not aware of the characteristics of these fires and are not properly prepared to fight them. Therefore, even a small metal fire can spread and become a larger fire in the surrounding ordinary combustible materials. Certain metals burn in contact with air or water (for example, sodium), which exacerbates this risk. Masses of combustible metals do not usually represent great fire risks because heat is conducted away from hot spots so efficiently that the heat of combustion cannot be maintained. In consequence, significant heat energy is required to ignite a contiguous mass of combustible metal. Generally, metal fires are a hazard when the metal is in the form of sawdust, machine shavings or other metal "fines", which combust more rapidly than larger blocks due to their increased surface area. Metal fires can be ignited by the same ignition sources that would start other common fires.

Care must be taken when extinguishing metal fires. Water and other common firefighting agents can excite metal fires and make them worse. The National Fire Protection Association recommends that metal fires be fought with

dry powder extinguishing agents that work by smothering and heat absorption. Different metals require different agents and for a particular metal, agents cannot necessarily be substituted for one another. The most common agents are sodium chloride granules and graphite powder. In recent years, powdered copper has also come into use. These dry powder extinguishers should not be confused with those that contain dry chemical agents. The two are not the same, and only dry powder should be used to extinguish a metal fire. Using a dry chemical extinguisher in error, in place of dry powder, can be ineffective or actually increase the intensity of a metal fire.

Class C (US)/Class E (AU)/Unclassified (EU): Electrical

"Electrical fire" redirects here. Not to be confused with Electric fire.

Damage from energized fallen power line caused by Hurricane Maria in Puerto Rico. Fires predominantly involving electricity have different classifications in each of the three systems. They are classified as a "Class E" fire under the Australian system, "Class C" under the American system and are classified based on the ignited fuel type under the European system (which previously shared the "Class E" classification with the Australian system). Electrical fires are fires involving potentially energized electrical equipment. This sort of fire may be caused by short-circuiting machinery or overloaded electrical cables. These fires can be a severe hazard to firefighters using water or other conductive agents, as electricity may be conducted from the fire, through water, to the firefighter's body, and then earth. Electrical shocks have caused many firefighter deaths.

Electrical fire may be fought in the same way as an ordinary combustible fire, but water, foam, and other conductive agents are not to be used. While the fire is or possibly could be electrically energized, it can be fought with any extinguishing agent rated for electrical fire. Carbon dioxide CO2, NOVEC 1230, FM-200 and dry chemical powder extinguishers and even baking soda are especially suited to extinguishing this sort of fire. PKP should be a last resort

solution to extinguishing the fire due to its corrosive tendencies. Once electricity is shut off to the equipment involved, it will generally become an ordinary combustible fire.

Class F (EU/AU)/Class K (US): Cooking oils and fats (kitchen fires)

Laboratory simulation of a chip pan fire: a beaker containing wax is heated until it catches fire. A small amount of water is then poured into the beaker. The water sinks to the bottom and vaporizes instantly (boil over), ejecting a plume of burning liquid wax into the air.

Fires involving cooking oils and fats are classified as "Class F" under the European and Australian systems, and "Class K" under the American system. Though such fires are technically a subclass of the flammable liquid/gas class, the special characteristics of these types of fires, namely the higher flash point, are considered important enough to recognize separately. Some special extinguishers designed for this use smother the fire by turning the oil into a foam. A water mist can also be used. As with Class B fires, a solid stream of water should never be used to extinguish this type because it can cause the fuel to scatter, spreading the flames. Appropriate fire extinguishers may also have hoods over them that help extinguish the fire. Sometimes fire blankets are used to stop a fire in a kitchen or on a stove.

Fire Class	Type of Material	Examples	Type of Extinguishers				
			Water	Dry Powder	CO2	Foam	Wet Chemical
A	General Combustibles	Wood, Paper, Dry Pulps	✓	✓		✓	✓
B	Flammable Liquids	Gasoline, Solvents, Paints		✓	✓	✓	
C	Flammable Gases	Methane, Butane, Cyclohexane		✓			
D	Combustible Metals	Magnesium, Aluminum, Potassium, Lithium		✓			
E	Electical Equipment	UPS, Sockets, Computers, Motors, Panels		✓	✓		
F	Cooking oils or fats	Chip Pans (Used for deep frying) made from aluminum or iron					✓

Table: Fire Types and Fire Extinguishers

The following are the types of available fire extinguishers.

- Water
- Dry Powder
- CO_2
- Foam
- Wet Chemical

Water Extinguishers

Compatible to mitigate Class A fires. Includes fire due to wood, paper, cardboard, coal, fabrics, or dry pulps. Installed near exit locations of hospitals, offices, etc.

When water is sprayed on the fire it has a cooling effect, reducing heat transfer (remember fire triangle) gradually eliminating heat element.

Label color on fire extinguisher is Red.

There are 3 types of water extinguishers:

Jet: Extend less surface area, consuming more time and water to mitigate fire.

Spray: Covering more surface areas requires less time to diminish fire but may require more water.

Mist: They are lightweight and have proper flow control. The rate of spraying ranges between 250-300 microns of water droplets forming a layer of heat with high precision. The droplet size of fewer than 250 microns can cause water droplets to evaporate and cannot mitigate the fire. On the other hand, higher particle size results in more water wastage. Sometimes able to handle Class B fires when added with suitable additives.

Dry Powder Extinguishers

They are compatible to mitigate Class A, B, C, D, and E fires. It is not recommended for use in confined spaces which may cause more confusion, difficult cleaning, and suffocation issues. We may find these types of fire extinguishers in the chemical, pharmaceutical, petroleum industries, etc.

Just like water type, they too cause barriers but in between oxygen and fuel ultimately breaking the fire triangle.

Label color on fire extinguisher is Blue.

CO2 Extinguishers

They are compatible to mitigate Class B and E fires. We can find these types of fire extinguishers in paint industries or construction sites wherever flammable liquids or electrical fire hazards may occur.

Carbon dioxide is typically stored in a liquid form. When released from the nozzle, it converts into gas. CO2 gas, when it comes in contact with the fire, replaces the oxygen with the help of high pressure. This eliminates the oxygen in the fire triangle, which results in a mitigated fire.

Label color on fire extinguisher is Black.

Foam Extinguishers

Compatible to mitigate Class A and B fires. These types of extinguishers are found in all places mentioned in the water extinguisher plus flammable metals.

Foam when applied on fire, reduces the heat and creates a barrier between fuel and heat, eventually mitigating the fire.

Label color on fire extinguisher is Cream White.

Wet Chemical Extinguishers

Compatible to mitigate Class A and F fires. Found in commercial and industrial kitchens and restaurants, wet chemicals effectively handle fires caused by combustible cooking media such as oils and fats.

Wet chemicals when sprayed, convert to foam and form a barrier between oil and heat, which mitigates the fire gradually.

Label color on fire extinguisher is Yellow.

Each fire type requires a different extinguisher to mitigate. Hence, the fire extinguishers must be used after detailed and optimized analysis of suitability, cost, resources, and practical.

Storage of flammable liquids

Flammable-barrel liquid

- A flammable liquid is considered to have a flash point below 32°C.
- All flammable liquids must be stored in approved containers and never in an open container to ensure compliance with fire safety regulations.
- Tanks of flammable liquids should be stored in suitable cabinets.
- Containers and cabinets for flammable liquids must be clearly marked to indicate that they contain flammable substances.

Storage of compressed gas cylinders

The following storage conditions must be observed in order to ensure fire safety.

- Storage areas for compressed gas cylinders must be located away from vehicles and heat sources.
- Cylinders with fuel gas must be separated from cylinders with oxygen.
- Valve caps must be in place during storage and transport.
- Empty cylinders must be segregated from full cylinders.
- All storage areas must be labelled.
- All cylinders must be stored in an upright position.
- Restraining chains or straps should be used to prevent gas cylinders from falling out of storage areas.

List of fire protection equipment in the pharmaceutical industry.

- Fire alarm systems
- Fire detection systems
- Loudspeaker system
- Dry chemical fire extinguishing systems
- Foam extinguishing system
- ADW Linear heat detection system
- Water mist fire suppression system
- Portable fire extinguishers
- Net agent suppression system
- Smoke Detectors

List of used literature.

1. World Health Organization 2019 The legal and regulatory framework for community pharmacies in the WHO European Region
2. European Commission Directorate-General for Employment, Social Affairs and Inclusion Unit B.3 Manuscript completed in December 2015 Guide to prevention and good practice. Occupational health and safety risks in the healthcare sector
3. Reese, Charles D. Occupational Safety and Health: fundamental principles and philosophies. Crc Press, 2017. 403 p.
4. Phil Hughes, Ed Ferrett. Introduction to Health and Safety at Work: for the NEBOSH National General Certificate in Occupational Health and Safety. Routledge, 2015. 676 p.
5. Pedro M. Arezes, João S. Baptista, Mónica P. Barroso. Occupational and Environmental Safety and Health. Springer International Publishing, 2019. 765 p.
6. Thomas P Fuller. Global Occupational Safety and Health Management Handbook.CRC Press, 2019. 359 p.
7. Karl H.E. Kroemer. Fitting the human introduction to ergonomics. Human factorsengineering. Boca Raton: CRC Press, 2017. 480 p.

Information resources, including the Internet

1. World Health Organization http://www.who.int/
2. Occupational Safety and Health Administration (OSHA) https://www.osha.gov/workers
3. The National Institute for Occupational Safety and Health (NIOSH) https://www.cdc.gov/niosh/index.htm
4. OSHAcademyhttps://www.oshacademy.com/index.html