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“28” August 2020

THEME 6 for practical lessons of the discipline life safety for first-year students of the pharmaceutical department:

legal and organizational issues of life safety and labor protection of medical and pharmaceutical workers

Vinnitsa 2020

**Occupational safety and health** (**OSH**) is a multidisciplinary field concerned with the [safety](https://en.wikipedia.org/wiki/Safety), [health](https://en.wikipedia.org/wiki/Health), and [welfare](https://en.wikipedia.org/wiki/Quality_of_life) of people at [work](https://en.wikipedia.org/wiki/Employment). The goal of occupational safety and health programs is to foster a safe and healthy work environment. OSH may also protect co-workers, family members, employers, customers, and many others who might be affected by the workplace environment.

In common-law jurisdictions, employers have a common law duty to take reasonable care of the safety of their employees. Statute law may in addition impose other general duties, introduce specific duties, and create government bodies with powers to regulate workplace safety issues: details of this vary from jurisdiction to jurisdiction.

As defined by the [World Health Organization](https://en.wikipedia.org/wiki/World_Health_Organization) (WHO) "occupational health deals with all aspects of health and safety in the workplace and has a strong focus on primary prevention of hazards." [Health](https://en.wikipedia.org/wiki/Health) has been defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Occupational health is a multidisciplinary field of [healthcare](https://en.wikipedia.org/wiki/Healthcare) concerned with enabling an individual to undertake their [occupation](https://en.wikipedia.org/wiki/Job), in the way that causes least harm to their health. It contrasts, for example, with the promotion of health and safety at work, which is concerned with preventing harm from any incidental [hazards](https://en.wikipedia.org/wiki/Hazards), arising in the workplace.

Since 1950, the [International Labour Organization](https://en.wikipedia.org/wiki/International_Labour_Organization) (ILO) and the [World Health Organization](https://en.wikipedia.org/wiki/World_Health_Organization) (WHO) have shared a common definition of occupational health. It was adopted by the Joint ILO/WHO Committee on Occupational Health at its first session in 1950 and revised at its twelfth session in 1995. The definition reads:

**"The main focus in occupational health is on three different objectives: (1) the maintenance and promotion of workers’ health and working capacity; (2) the improvement of working environment and work to become conducive to safety and health and (3) development of work organizations and working cultures in a direction which supports health and safety at work and in doing so also promotes a positive social climate and smooth operation and may enhance productivity of the undertakings. The concept of working culture is intended in this context to mean a reflection of the essential value systems adopted by the undertaking concerned. Such a culture is reflected in practice in the managerial systems, personnel policy, principles for participation, training policies and quality management of the undertaking."**

— ***Joint ILO/WHO Committee on Occupational Health***

"Occupational health should aim at: the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations; the prevention amongst 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; the placing and maintenance of the worker in an occupational environment adapted to his physiological and psychological capabilities; and, to summarize, the adaptation of work to man and of each man to his job.

**The responsibility of the employers as a basic principle**

With Framework Directive 89/391 EEC, the European legislator has established a fundamental law on occupational safety and health which defines common principles of prevention in the company and for the protection of the workers. It is essential to know that EU legislation does not mention the responsibility of management, but rather only the obligations and the responsibility of the employer with regard to safety and health at work: “The employer shall have the duty to ensure the safety and health of the workers in every aspect related to the work”.

The employer is legally defined as “any natural or legal person who has an employment relationship with the worker and has responsibility for the undertaking or establishment”. This legal definition has to be interpreted in light of the European and national laws on corporate organization and companies. In forms of sole proprietorship or partnerships, shop owners are also the persons responsible in the sense of the “employer”. In corporate companies, the acting organ or managing board of the legal entity acts as employer in the sense of the European Framework Directive.

Neither third persons entitled by the employer nor any obligation attributed to a worker have any influence on the basic principle of employers’ responsibility. This means that the employer can only delegate tasks that contribute to the fulfillment of the duties and obligations, but cannot delegate responsibility for safety and health at work in general. The delegation must be specific and precise and the employer is responsible for selection, instruction and supervision of any third person.

**Obligations of the employer**

The European legislative framework on occupational safety and health (OSH) is rather target oriented and therefore requires high standards from OSH management in the company in order to meet the aims and obligations set out by the different regulations. The basic principle of target orientation is set out in Art.6 Directive 89/391 EEC that obliges the employer to constantly guarantee a better level of protection of workers’ health and safety and aim at a permanent improvement of working conditions. In this context, the employers have to keep themselves informed about latest developments and state of the art technological improvements and work place design. They also have to develop a prevention policy that covers all aspects of safety and health at work.

The Framework Directive defines a bundle of measures that the employer has to carry out in order to fulfill his legal responsibility for the safety and health of the workers. The most important ones are:

* Carry out safety and health risk assessments at the workplaces in the company and provide documentation of the results. This includes the obligations of implementing preventive measures based on the results of the risk assessment, in accordance to the principles of prevention as laid down in Art.6 of the Framework Directive and [OSH risk assessment methodologies](https://oshwiki.eu/wiki/Occupational_safety_and_health_risk_assessment_methodologies);
* Inform the workers about safety and health risks as well as about adequate measures of protection and prevention (Art. 10);
* Provide appropriate safety and health training measures and ensure that each worker can participate in accordance to the rules laid down in Art.12, which declares that training must take place on recruitment, in the event of a transfer or a change of job, in the event of the introduction of new work equipment or a change in equipment, in the event of the introduction of any new technology.
* Take care of measures of emergency response (incl. evacuation procedures, fire fighting and medical services, Art. 8);
* [Consult workers and their representatives](https://oshwiki.eu/wiki/Occupational_safety_and_health_management_systems_and_workers%E2%80%99_participation) and allow them to [participate in the decision making process concerning safety and health at work](https://oshwiki.eu/wiki/Methods_and_effects_of_worker_participation) as foreseen in the EU-Directives;
* Ensure the health surveillance of the workers in accordance with the national laws on occupational medical services (Art. 14).

In any case, the employer must ensure that the designated workers or service providers have the required capabilities, means, resources, expertise and information to successfully organize and carry out the [designated prevention measures](https://oshwiki.eu/wiki/Category:Job_design). If the employer does not comply with these provisions, it may be possible to accuse him/her of organizational negligence, a charge that could be substantiated with respect to personal responsibilities as per the national rules in penal or tort law.

**Challenges of managing occupational safety and health compliance**

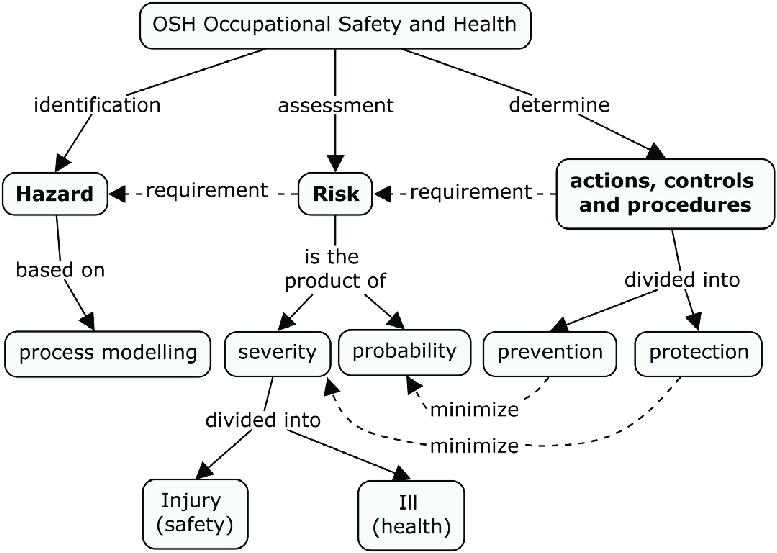
The current European legislation on safety and health at work is influenced by the Scandinavian tradition of regulating occupational safety and health and by the definition of the working environment laid down in the international conventions of the International Labour Organization. The European legislation is based on a dynamic, holistic and preventive concept of [safety and health at work](https://oshwiki.eu/wiki/Category:What%27s_OSH), which obliges the employer to constantly improve for the benefit of the workers.

The general prevention concept is primarily based on describing the aims and objectives rather than giving concrete prescriptions on thresholds, measurements or means. On the one hand, this gives the employer the opportunity to decide on the most adequate method to apply to the business. On the other hand, it requires a higher level of knowledge of how the goals can be reached in order to comply with legislation. In practice, this open approach has been discussed controversially because it seems to favour large organizations which dispose of a specialized management.

**Models of OSH management**

The EU Directives on safety and health at work do not establish any strict regulatory framework on OSH management. It is up to the employers to decide on how to organize their business. Traditional OSH management used to set the focus on the avoidance of punishment and experts’ knowledge. The main goal was establishing a regulatory compliance. In contrast, modern management aims to improve performance, activate workers and reach goals beyond legal prescriptions. Health and safety management is seen as a part of the general company’s management. Therefore, OSH experts strongly recommend some basic elements that should be taken into account:

* Measurable objectives for safety and health should be set and be part of the company’s policy. Objectives and policy are transparent and supported by management and the workers;
* Measures should be implemented following defined processes and responsibilities. Workers and their representatives should be involved;
* Actions shall be based on a risk assessment and not only cover corrective, but also preventive measures;
* Performance in safety and health at work should be checked on a regular basis with the of measurable performance indicators;
* Lessons should be learned and be mainstreamed in an improvement cycle. Results of the lessons learned should be promoted in training sessions for management and workers.



At the current time, many companies use management systems to ensure that regulatory prescriptions are met. The big advantage of OSH management systems is that they provide a clear description of how processes concerning safety and health can be organized in the company. The International Labour Organization defines an [OSH management system](https://oshwiki.eu/wiki/What_are_occupational_safety_and_health_management_systems_and_why_do_companies_implement_them%3F) as “a set of interrelated or interacting elements to establish OSH policy and objectives and to achieve those objectives”.

The systems are usually based on industrial standards and can be implemented separately or as part of an integrated management approach together with quality management and/or environmental management systems. Some standards and guidelines are developed by International Organizations; national standards exist in various EU Member States. Some of them are industry specific or especially designed for use in small and medium enterprises. They are often promoted by labour inspectorates, accident insurance bodies, or other prevention services.

Internationally established guidelines and standards of [OSH management system](https://oshwiki.eu/wiki/What_are_occupational_safety_and_health_management_systems_and_why_do_companies_implement_them%3F) are ILO-OSH 2001, a guideline for OSH management developed by the International Labour Organization and OHSAS 18001. The later one has also become a national standard in various European countries and can be certified worldwide. It is often combined with other management systems of the International Organization for Standardization. Additionally, there are various national standards for some of them, especially for small and medium enterprises or for certain industries which are promoted by national institutes or prevention services.

OSH management systems usually based on the “Plan-do-check-act” (PDCA) model and aim to implement a continuous improvement process in the company which is integrated part of modern quality management (so-called “Deming Cycle”). So, generally speaking, management systems fit well to the aim of European OSH Directives for permanently improving the level of prevention in the company. However, one should keep in mind that the goals of improvement are in line with the enhancement of the prevention level in the company, which is the aim of the EU legislation.

OSH management systems are designed for supporting the management in complying with legal requirements. The OHSAS 18001 standard for examples requires the employer to have an overview available, one that compiles all OSH legislative requirements relevant for the company. Such an overview should include all specific and detailed requirements, even from the EU legislation on machinery and on chemical substances. It can then be used to check where adequate measures are already in place, where plans for improvement (and compliance) are still necessary, and to develop a strategy for assuring compliance.

However, when deciding to implement an OSH management system, one should remember that there is no homogeneous standard for OSH management systems and no common definition of scope and processes. Even though all [OSH management systems](https://oshwiki.eu/wiki/What_are_occupational_safety_and_health_management_systems_and_why_do_companies_implement_them%3F) serve for implementing the company’s OSH policy and for managing safety and health risks, the employer should always need to adapt it to the situation in the company. This means that each employer has to ensure that all relevant safety processes, working conditions and specific risks are covered in order to meet legal requirements.

**Strategies for improving occupational safety and health management performance**

Among the most common errors that occur is the inadequate response to new and emerging risks at the workplace. The most prominent example is the issue of psycho-social and organizational risks, despite the fact that they currently belong to the most important OSH risks factors. There are indicators that the [management of psycho-social risks](https://oshwiki.eu/wiki/Work-related_stress:_Nature_and_management) not only remains an uncovered issue in OSH management, but also in certification audits. Further frequent points of non-compliance with legal provisions are:

* Focusing on accident prevention only instead of ill-health prevention in general
* Not including external service providers (e.g. maintenance workers or cleaners)
* Not including workplaces of temporary workers
* Not meeting “formalities” (e.g. documentation of risk assessments)
* Not involving workers or their representatives.

In practice, the quality of [OSH management](https://oshwiki.eu/wiki/What_are_occupational_safety_and_health_management_systems_and_why_do_companies_implement_them%3F) is highly dependent on the prioritization of the topic in the management culture and to the management commitment for safety and health at work. In other words, OSH management can only be successful if it is handled with the same commitment as any other field of management in the company. This can be ensured by setting clear and measurable objectives that are followed with equal priority to other key data in the company, defining processes and responsibilities, ensuring monitoring and improving safety culture and awareness of workers and management representatives.

For a more holistic approach that includes the promotion of the health of the workers, it is recommended that OSH management be combined with measures of [work place health promotion](https://oshwiki.eu/wiki/Category:Workplace_Health_Promotion) or health management. Concepts exist that combine classical OSH aims like the reduction of sick leave costs with the promotion of productivity as well as with the promotion of individual resources.

When the employer lacks expertise, it is advantageous to contact external specialists in order to improve OSH management performance. Such services do not have to be cost-intensive. In many EU Member States, governmental institutes, insurance bodies or sector organizations provide services for improving OSH management, in particular for small and medium enterprises.

**Consequences of non-compliance and aspects of liability**

The principle of being responsible for complying with the legislation on safety and health at work finds its expression in the rules of liability for the employer. These rules are established by national law and can include financial liability for workers’ compensations in the case of ailment, fines in cases of administrative offences, and also personal sanctions in criminal law.

***Financial compensation of workers***

If the employer does not comply with the duties and obligations laid down in the European and national laws on safety and health at work, workers who become ill or get involved in accidents due to negligence can claim for indemnification and financial compensation for non-material damages. The procedure depends on the national systems for workers’ compensation and hence, on the company’s insurance status.

If the company is insured by law (“statutory accident insurance”) or by private contract, the worker will usually receive compensation from the body of insurance. In an act of gross negligence by the employer, the body of insurance might have the right to reject the payment or to claim for regress. If the company does not dispose of any insurance coverage, the employer might be sentenced to compensate the worker from company resources.

***Personal criminal liability and tort law***

Single board members or management representatives might also be individually responsible in cases of gross negligence, depending on the national rules in criminal or tort law. This can be the case if they did not comply with the designated duties on safety and health at work or if they neglected duties of selection and supervision of a designated person.

This personal responsibility can include convictions because of negligence, homicide or bodily harm. The personal criminal liability might be threatened with imprisonment depending to national legislation. The tort law might constitute personal financial compensation.

***Fines for non-compliance***

Below criminal liability, the national rules might foresee fines for administrative offences. They include cases of not complying with OSH legislation. Even without any consequences for workers’ health employers can be fined by labour inspectorates. The fines depend on national legislation and the systems of labour inspection, which can vary from case to case. In some countries (like the Netherlands), fines can be substantially increased in cases of “non-compliance created economic benefits”. The economic benefit can then be added up to the normal fine. Labour inspectorates in some EU Member States take account of certified management systems when planning their inspection schemes in a way that sees them controlling them less frequently or only in re-active inspections (responding to complaints or accidents). This takes account of the fact that a certified OSH management probably contributes to the better organization of safety and health in the company. However, labour inspections can still control the fulfillment of the legal obligations and can impose fines for non-compliance. [Poor OSH performance](https://oshwiki.eu/wiki/The_importance_of_good_leadership_in_occupational_safety_and_health) can also be fined by negative incentives or extra premiums: In this case, employers whose workers are frequently involved in work place accidents can be obliged by the insurance body to pay an extra premium for bad OSH performance.