

SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – I – Industrial Safety – SBT1609

Introduction

Industrial safety must be an integral part of any industrial undertaking; it must be built in at the design stage, in production planning and in operator training. The aim must be to make every individual in industry have more regard not only for his own personal safety, but also for the safety of others.

Concepts of management in Safety

- (1) Provide workers with a safe work environment.
- (2) Conduct routine/regular workplace inspections.
- (3) Provide Personal Protective Equipment.
- (4) Develop and implement safe work procedures and rules.
- (5) Provide on-going safety training
- (6) Enforce safety rules and appropriate discipline.
- (7) Provide on-going property conservation practices.

Employee orientation program

All new employees must attend the Safety Orientation Session prior to starting work within their assigned area. This session will be conducted under the direction of the Safety Director and in coordination with Human Resources. Upon completion of the Safety Orientation Session, each new employee will be required to acknowledge that they have received, understand, and will abide by the industry's Safety Program. All participants must sign a statement verifying that they have completed the session. This report will be filed in the employee's personnel file.

The following topics are covered in the Safety Orientation Session:

- **1.** Company History
- 2. Safety Program/Policy & Work rules
- **3.** Responsibilities
- **4.** Safety Education/Training
- **5.** Safety Audit/Inspections
- 6. Accident Reporting/Investigation Requirements
- 7. First Aid & Blood borne Pathogens
- 8. Personal Protective Equipment
- 9. Tool & Equipment Use
- **10.** Material Handling
- **11.** MachineGuarding
- **12.**Hazard Communication
- **13.**Emergency Action

Safety Rules

All safety rules must be obeyed. Failure to do so will result in strict disciplinary action.

- **1.** All injuries must be reported as soon as possible.
- 2. No horseplay, alcohol, or drugs allowed on premises. No alcohol usage allowed

during

a. Lunch break.

- **3.** PPE must be worn as prescribed by management.
- **4.** All tools/equipment must be maintained in good condition.
- **5.** Only appropriate tools shall be used for specific jobs.
- **6.** All guards must be kept in place.
- **7.** No spliced electrical cords/wiring allowed.

Safety committee

General functions of the Safety Committee can include:

- (1) Identifying workplace hazards
- (2) Enforcement of Safety Rules
- (3) Measuring safety performance
- (4) Reducing frequency/severity of injuries
- (5) Creating safety policies

(6) Developing and monitoring safety programs Specific tasks of the Safety Committee can include:

- (1) Conducting self-inspections of the workplace
- (2) Review employee reports of hazards
- (3) Assist in safety training
- (4) Creating safety incentive programs
- (5) Publish/distribute safety newsletter
- (6) Inspect PPE
- (7) Post safety posters/slogans on bulletin board
- (8) Identify Light Duty Jobs

Emergency action plan

The Emergency Action Plan (EAP) is in place to ensure employee safety from fire and other emergency. At the time of an emergency, all employees should know

what type of evacuation is necessary and what their role is in carrying out the plan. In some emergencies total and immediate evacuation will be necessary. In other emergencies only partial evacuation may be necessary.

When a fire is detected it is necessary that the fire alarm pull station be activated as soon as possible. The fire alarm will notify the emergency response team who will perform assigned duties. The activation of the alarm will also notify the local fire department.

In the event of bomb threat, toxic chemical release, hazardous weather, or other emergencies - notification will be made over the public address system. In the event of fire, bomb threat, or toxic chemical release; employees are to proceed to the nearest available and safe exit and leave the building as soon as possible. Floor plans (maps) and exits have to be posted in each department.

ALARM SYSTEMS

- Alarm systems can be divided into four groups: <u>local</u>, <u>auxiliary</u>, <u>central station</u>, and <u>proprietary</u>.
- ≻All types of alarm systems should be equipped with a signal system that clearly communicates to all persons in the building, plant, or laboratory.
- ➤Whenever an alarm is sounded in any portion of the building or area, all employees must know what the sound means.

>Local Alarm Systems

- A local alarm consists simply of bells, horns, lights, sirens, or other warning devices right in the building.
- Local alarms are generally used for life protection that is, to evacuate everyone and thus limit injury or loss of life from the fire.
- \triangleright A local alarm can be tied in with another system to call the fire department.
- Local alarm systems are inexpensive, available from a wide range of suppliers, and easy to install.
- > Auxiliary Alarm Systems (supplementary)
- Auxiliary alarm systems are even less expensive than local alarm systems.
- Such a system simply ties a fire detector to a nearby fire call box. In effect, it becomes a transmit station triggered by fire detectors inside the building.

>FIRE-SAFE BUILDING DESIGN AND SITE PLANNING

- The objective of fire safety is primarily to <u>protect life</u> and secondly <u>property</u> from the destruction of fire in a building.
- ➢ Building design and construction must take into account a wide range of fire safety features. Not only the interiors and contents of buildings are protected from the dangers of fire, but the building site it self must have adequate water supplies and easy accessibility by the fire department.
- Architects, builders, and owners may assume that state codes provide adequate measures; however, these codes specify only minimal measures for fire safety. Planning and construction based upon such codes may limit fire safe design seriously.

Building Evacuation

- ▶ Proceed to nearest exit in an orderly fashion
- ► Assemble at least 100 feet from building
- > Provide emergency crews with information about people still in the building
- > Provide information to emergency crews about the reason for evacuation
- Never re-enter a building until instructed to by the police department, fire department

Disaster Control (FIRE FIGHTING EQUIPMENTS)

Fire is a chemical reaction in which oxygen is combined with a gaseous or vaporous fuel. Note that, even if the fuel is a solid (e.g. wood) or a liquid (e.g. petrol) it is the vapours given off when the fuel is heated that burn. This rapid oxidation produces heat and light (flames). Fire can usually take place only when these three elements are present: • Oxygen • Fuel • Heat (energy) These 3 elements make up what is commonly called the 'Fire Triangle.

Essentially, fires are extinguished by taking away one or more of the elements in the fire tetrahedron. This can be achieved by

• Removal or separation of un burnt fuel (eg turn off the gas)

•Removal or dilution of the oxygen supply (eg smothering the fire with a fire blanket or an inert gas)

•Removal of the heat of the oxidation reaction (eg spraying the fuel with water)

•Inhibiting the chain reaction by modifying the combustion chemistry

A **fire extinguisher**, or **extinguisher**, is an active fire protection device used to extinguish or control small fires, often in emergency situations. It is not intended for use on an out-ofcontrol fire, such as one which has reached the ceiling, endangers the user (i.e., no escape route, smoke, explosion hazard, etc.),

Different classes of fire extinguishers

Class A: Extinguishers are for ordinary combustible materials such as paper, wood, cardboard and most plastics

Class B: Fires involve flammable or combustible liquids such as gasoline, kerosene and oil.

Class C: Fires involve electrical equipment such as appliances, wiring, circuit breakers and outlets

Class D: Fires that involve combustible metals such as magnesium, potassium and sodium

The selection of a suitable extinguisher is primarily influenced by the following factors

•The size and rate of fire spread

•The Class of fire (i.e. type of materials involved)

•The training and capabilities of the person using the extinguisher

Use of fire extinguisher

There are a number of different types of portable fire extinguishers, each can be identified by the colour coding and labelling. Check that the extinguisher you intend to use is suitable for the type of fire encountered eg a water extinguisher must never be used on any fire involving electrical equipment.

There are four (4) basic steps for using modern portable fire extinguishers. The acronym **PASS** is used to describe these four basic steps

1. **Pull** (Pin):Pull pin at the top of the extinguisher, breaking the seal. When in place, the pin keeps the handle from being pressed and accidentally operating

the extinguisher. Immediately test the extinguisher. (Aiming away from the operator) This is to ensure the extinguisher works and also shows the operator how far the stream travels

2. Aim: Approach the fire standing at a safe distance. Aim the nozzle or outlet towards the base of the fire.

3. **Squeeze**: Squeeze the handles together to discharge the extinguishing agent inside. To stop discharge, release the handles.

4. **Sweep**: Sweep the nozzle from side to side as you approach the fire, directing the extinguishing agent at the base of the flames. After an A Class fire is extinguished, probe for smoldering hot spots that could reignite the fuel.

Water Extinguisher

Water extinguishers are extinguishers that contain water and compressed gas. The water is ejected through the nozzle by a CO2 gas cartridge or by stored pressure typically nitrogen gas. These are used on Class A fires (wood, paper, fabric). They are typically 9 to 10 liters capacity and can project a jet of water about 6 meters. For the best effect the water stream should be directed at the burning material.

Foam extinguisher

The contents are ejected about 4 to 5 meters by a gas cartridge or by stored pressure and they are about 9 liters in capacity. These are used on Class B fires (liquids such as petrol, paints, oils etc). For the best effect the foam should be applied to fall as lightly as possible onto the burning material. This can be achieved by applying the foam to a rear wall in the case of an enclosed area, or if in an open space aiming the foam to strike the ground just short of the fire so that it flows gently over the burning fue

Dry Chemical Powder extinguisher

The contents are ejected by a gas cartridge or by stored pressure. They are used on Class B fires, that is on flammable liquid fires to assist foam in the combined- agent suppression. They are safe to use on live electrical equipment, but are generally not preferred for this role because of the clean-up afterwards. They range in size from 1kg to 11kg, though 9 kg is the most common. The 'standard' powder is sodium bicarbonate, but a number of high performance powders are also in use. Dry chemical powder is most effectively applied to flammable liquid fires in a low sweeping motion so as to apply a cloud of powder over the fire area. There is a possibility of re-ignition once the powder has dispersed from concealed flames or hot spots. When applied to 'running fuel fires' the powder should be directed first at the lowest parts of the fire and gradually worked upwards.DCP extinguishes are rated as either 'ABE' or 'BE'. This will be indicated on the label.

Carbondioxide extinguisher

They are used as a first attack on electrical fires. The portable units vary in size from 2.5 kg to 7 kg. CO2 is a colorless, odorless gas, which does not support combustion. It is not poisonous but is suffocating in large quantities. The gas is discharged through a wide 'horn' discharge nozzle and the gas stream projects for 1 to 2 meters. This discharge is accompanied by a large roar and the gas is intensely cold, and can cause frostbite. It is

applied in a low sweeping motion at the base of the fire, and the possibility exists for reignition after the gas disperses. However it leaves no mess or residue and is therefore preferred for electrical fires.

JOB SAFETY ANALYSIS

A Job Safety Analysis (JSA) is one of the risk assessment tools used to identify and control workplace hazards.

JSAs are usually developed when directed to by a supervisor, when indicated by the use of a first tier risk assessment and whenever a hazard associated with a task has a likelihood rating of 'possible' or greater. A JSA is a documented risk assessment developed when company policy directs people to do so.

Generally, high consequence, high likelihood tasks are addressed by way of a JSA.

High consequence, high likelihood tasks include, but are not limited to, those with:

A history of, or potential for, injury, harm or damage such as those involving:

- 1. Fire, chemicals or a toxic or oxygen deficient atmosphere.
- 2. Tasks carried out in new environments.
- 3. Rarely performed tasks.
 - 4. Tasks that may impact on the integrity or output of a processing system.

The JSA or JHA should be created by the work group performing the task. Sometimes it is xpedient to review a JSA that has been prepared when the same task has been performed before but the work group must take special care to review all of the steps thoroughly to ensure that they are controlling all of the hazards for this job this time. The JSA is usually completed on a form.

The most common form is a table with three columns (although each company has a variation with many having five or six columns). The headings of the three columns are (1) Job Step (2)Hazard (3) Controls. A Hazard is any factor that can cause damage to personnel, property or the environment (some companies include loss of production or downtime in the definition as well). A Control is any process for controlling a hazard. The work group firstly breaks down the entire job into its component steps. Then, for each step, hazards are identified. Finally, for each hazard identified, controls are recorded in the 3rd column.

When the task is complete it is often of benefit to have a close-out or "tailgate" meeting, to discuss any lessons learned so that they may be incorporated into the JSA the next time the task is undertaken.

Four basic stages in conducting a JSA are:

- 1. selecting the job to be analyzed
- 2. breaking the job down into a sequence of steps
- 3. identifying potential hazards
- 4. determining preventive measures to overcome these hazards

Example of JSA form is given below

Sequence of Events	Potential Accidents or Hazards	Preventive Measures

Types of JSA

1. Physical Job safety analysis

JSA which deals with mechanical failure, falling, skidding etc., are classified thus

2. Chemical Job safety analysis

JSA which deals with chemicals like flammables, combustibles, explosives etc., are classified thus

High pressure and high temperature operations: Install and operate the equipment within suitable barricade, if required, using appropriate safety accessories and operating in full compliance with local safety codes and rules. Establish training procedures to ensure that any person handling the equipment knows how to use it properly.

Maintain the equipment in good condition and establish procedures for periodic testing to be sure that the vessel remains structurally sound.

Reactions involving highly reactive compounds such acetylene, butadiene, dioxane, ethylene oxide, oxygen and all strong oxidizing agents, must be handled cautiously. Close attention must also be given to any reactions that might release sudden surges of heat and pressure, and to any by-products or end-products suspected to have explosive or detonating properties. It is always advisable to run preliminary experiments using small volumes of reactants when starting work with new or unfamiliar materials. The amounts can be increased

later after it has been shown that the reaction proceeds smoothly with no indication of erratic or explosive behavior.

The maximum pressure and temperature at which any reactor or pressure vessel can be used will depend upon the design of the vessel and the materials used in its construction. Since all materials lose strength at elevated temperatures, any pressure rating must be stated in terms of the temperature at which it applies. Catalog listings for Parr reactors and pressure vessels show the maximum allowable working pressure at 350 °C for vessels made of Type 316 stainless steel (except certain high pressure/high temperature units which are rated at 500 °C). Pressures are shown in pounds per square inch gage pressure (psig) and in bars. The table of Pressure Rating Factors shown below provides a set of multipliers which can be used to convert pressure ratings for T316SS vessels from 350 °C to higher or lower temperatures. It can also be used to determine the pressure rating for a vessel of the same design made of a material other than T316 stainless steel.

Materials Of Construction

Type 316 Stainless Steel is an excellent material for use with most organic systems. A few organic acids and organic halides can, under certain conditions, hydrolyze to acetic, formic and other organic acids that are routinely handled in T316SS. T316SS is not normally the material of choice for inorganic acid systems. At ambient temperatures it does offer useful resistance to dilute sulfuric, sulfurous, phosphoric and nitric acids which readily attack T316SS in higher concentrations and temperatures. Halogen acids attack all forms of stainless steel rapidly, even at low temperatures and in dilute solutions. T316SS offers excellent resistance to surface corrosion by caustics, but this is misleading. Caustics can cause stress corrosion cracking in stainless pressure vessels. This phenomenon begins to appear at temperatures just above 100 °C and has been the most common cause of corrosion failure in stainless laboratory vessels. T316SS does offer good resistance to ammonia and to most ammonia Nominal Chemical Composition compounds.

Zirconium offers excellent resistance to hydrochloric and sulfuric acids but, as with Hastelloy B-2, oxidizing ions such as ferric, cupric and fluorides must be avoided. Zirconium also offers good resistance to phosphoric and nitric acids, and to alkaline solutions as well.

Lethal dose and lethal concentration : LD stands for "Lethal Dose". LD50 is the amount of a material, given all at once, which causes the death of 50% (one half) of a group of test animals. The LD 50 is one way to measure the shortterm poisoning potential (acute toxicity) of a material.

Toxicologists can use many kinds of animals but most often testing is done with rats and mice. It is usually expressed as the amount of chemical administered (e.g., milligrams) per 100 grams (for smaller animals) or per kilogram (for bigger test subjects) of the body weight of the test animal. The LD50 can be found for any route of entry or administration but dermal (applied to the skin) and oral (given by mouth) administration methods are the most common. Chemicals can have a wide range of effects on our health. Depending on how the chemical will be used, many kinds of toxicity tests may be required.

Since different chemicals cause different toxic effects, comparing the toxicity of one with another is hard. We could measure the amount of a chemical that causes kidney damage, for example, but not all chemicals will damage the kidney. We could say that nerve damage is observed when 10 grams of chemical A is administered, and kidney damage is observed when 10 grams of chemical B is administered. However, this information does not tell us if A or B is more toxic because we do not know which damage is more critical or harmful.

Therefore, to compare the toxic potency or intensity of different chemicals, researchers must measure the same effect. One way is to carry out lethality testing (the LD50 tests) by measuring how much of a chemical is required to cause death. This type of test is also referred to as a "quantal" test because it is measures an effect that "occurs" or "does not occur". LC stands for "Lethal Concentration". LC values usually refer to the concentration of a chemical in air but in environmental studies it can also mean the concentration of a chemical in water.

According to the OECD (Organisation for Economic Cooperation and Development) Guidelines for the Testing of Chemicals, a traditional experiment involves groups of animals exposed to a concentration (or series of concentrations) for a set period of time (usually 4 hours). The animals are clinically observed for up to 14 days.

The concentrations of the chemical in air that kills 50% of the test animals during the observation period is the LC50 value. Other durations of exposure (versus the traditional 4 hours) may apply depending on specific laws.

Acute toxicity is the ability of a chemical to cause ill effects relatively soon after one oral administration or a 4-hour exposure to a chemical in air. "Relatively soon" is usually defined as a period of minutes, hours (up to 24) or days (up to about 2 weeks) but rarely longer. In nearly all cases, LD50 tests are performed using a pure form of the chemical. Mixtures are rarely studied.

The chemical may be given to the animals by mouth (oral); by applying on the skin (dermal); by injection at sites such as the blood veins (i.v.- intravenous), muscles (i.m. - intramuscular) or into the abdominal cavity (i.p. - intraperitoneal).

The LD50 value obtained at the end of the experiment is identified as the LD50 (oral), LD50 (skin), LD50 (i.v.), etc., as appropriate. Researchers can do the test with any animal species but they use rats or mice most often. Other species include dogs, hamsters, cats, guineapigs, rabbits, andmonkeys. In each case, the LD50 value is expressed as the weight of chemical administered per kilogram body weight of the animal and it states the test animal used and route of exposure oral dministration; e.g., LD50 (oral, rat) - 5 mg/kg, LD50 (skin, rabbit) - 5 g/kg. So, the example"LD50 (oral, rat) 5 mg/kg" means that 5 milligrams of that chemical for every 1

kilogram bodyweight of the rat, when administered in one dose by mouth, causes the death of 50% of the testgroup.

If the lethal effects from breathing a compound are to be tested, the chemical (usually a gas orvapour) is first mixed in a known concentration in a special air chamber where the test animalswill be placed. This concentration is usually quoted as parts per million (ppm) or milligrams percubic metre (mg/m3). In these experiments, the concentration that kills 50% of the animals is called an LC50 (Lethal Concentration 50) rather than an LD50. When an LC50value is reported, it should also state the kind of test animal studied and the duration of the exposure, e.g., LC 50 (rat) -1000 ppm/ 4 hr or LC50 (mouse) - 5mg/m 3/ 2hr.

Inhalation and skin absorption are the most common routes by which workplace chemicals enter the body. Thus, the most relevant from the occupational exposure viewpoint are the inhalation and skin application tests. Despite this fact, the most frequently performed lethality study is the oral LD50. This difference occurs because giving chemicals to animals by mouth is much easier and less expensive than other techniques. However, the results of oral studies are important for drugs, food poisonings, and accidental domestic poisonings. Oral occupational poisonings might occur by contamination of food or cigarettes from unwashed hands, and by accidental swallowing.

SAFE HANDLING & OPERATION OF MATERIALS AND MACHINERIES

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When identifying the hazards related with machines, we shall consider: the type of machines, layout of machines, driven method, e.g. electricity, air and operating parameters, e.g. speed, pressure, temperature, size of cut, mobility, etc. Typical hazards related with operation of machines include:

**	mechanical:	
e.g. crushing, shea	aring, cutting or severing,	stabbing or puncture
*	high pressure fluid ejection	
*	electrical shock	
*	noise and vibration	
*	contact with extremes of temp	erature
*	ergonomics	

Types of hazards control measures: using prescribed machine guards, Using devices, e.g. sensor, gates, maintaining instructed distance during machine operations, Use

of automatic or semi-automatic fed and ejection/robots, Use of feeding tools, undergoing proper training programming, ,following (LOTO) procedures, wearing proper personal protective equipment(PPE) will reduces the risk level .To minimize the risk of accidents each *authorized* employee *shall* receive training in:

- Recognition of applicable hazardous energy sources
- Type and magnitude of the energy available in the workplace
- Methods and means necessary for energy isolation and control

The employer shall certify that employee training has been accomplished and is being kept up to date, also the certification shall contain employee names and dates of training.

.Types of machine guarding

• Fixed guard- these guards are used to prevent the entry into the point of operation, do not move when the machine is in operation .E.g.: Barrier guard, enclosure guard

• **Interlocked guard**- these are used when a fixed guard cannot be used which is either connected to machine controls or power source. It can be applied to the machines by mechanical, electrical, or pneumatic.

Adjustable guard

• Self-adjusting guard- these are used to push, pull, or sweep the operator's hands out of the danger zone during the machine operation. Example: Automatic Pull Backs

LOTO procedure

After January 1990, whenever replacement, major repair, or modification of a machine is performed, or whenever new machines or equipment are installed, they must be designed to accept a lockout device.

• Durable: Lockout and tagout devices must withstand the environment to which they are exposed for the maximum duration

• Standardized: Both lockout and tagout devices must be standardized according to either *color, shape, or size*

• Tagout devices must also be standardized according to *print and* format

• Tags must also include a legend such as:

- Do not start
- Do not open
- Do not close
- Do not energize
- Do not operate



• Substantial: Lockout and tagout devices must be substantial enough to minimize early or accidental removal

• Identifiable: Locks and tags must clearly identify the employee who applies them.

General instructions for Safe handling and operation of materials and machinery

1. Only those materials and machines which meet the essential requirements on safety & health be put into service.

2. All parts of a machine which cause danger of a person being trapped or cut must be equipped with guards or protective devices.

3. The operations for adjustment, cleaning, greasing and repairing must be performed with the machine turned off and the power source disconnected.

4. Loose clothing, loose hair or jewellery etc., must be avoided while operating a machine.

5. Every machine must be equipped with emergency stoppage mechanisms that make it possible to stop the machine safely under emergency.

6. Every person who uses a machine has to receive proper training and information on the risk that the work involves.

7. The danger zones of the machines must be marked with warnings and signs.

8. Proper illumination should be provided.

9. Operators should read and adhere to manufacturers operating manual and instructions.

10. Proper housekeeping/maintenance.

SAFETY EDUCATION AND PERIODIC TRAINING

Safety Education

It deals primarily in the development of mind, broadening one's knowledge in the field of safety by understanding the concept or principle of any hazardous material on the job activity. The cause for the hazard or the hazardous property of the material one handles can be ascertained easily through education and then it could be explained even to the uneducated employees through any kind of communication technique. This develops the consciousness, awareness and a

state of mental alertness among the workers to identify and prevent the hazardous situations.

Safety Training: Safety training is an extension of safety education which lies effectively in the use of safety work practices and techniques. The general benefits from the safety training are

1. Training activities indirectly demonstrate company's interest in employees which leads to good human relations at work.

2. Understanding the importance of safety and hence following safe work procedures in the operation of machines, equipments and handling materials

3. Training saves the time spent by the supervisor to instruct and correct

4. Knowing the techniques of fire fighting, first aid, lifting, stacking etc helps a lot in the accident prevention and in emergencies.

Level - Training Needs

Helper - Need for safety at work, hazards connected with his work, ways to safeguard **Operator** - Need for Safety, safety requirements of his job,his responsibilities

Supervisor - Hazards in the operations supervised and the technical skills to identify and prevent them, a broad knowledge of company's policy, techniques of supervision, human relations and communication skills.

Manager - Responsibility for safety, companys policy and direction, techniques to identify and control hazards, safety engineering and management, human relations and communication.

Training programmes on specific areas like fire extinguishing, first aid , noise, industrial hygiene, major hazards control during emergencies, uses of personal protective equipments must be covered. Training can be given by

On-Job training
Lecture Method
Group Discussions
Case Studies
Learning by doing
Demonstration and visit

SAFETY AUDIT

Safety audits are conducted in order to assess the degree of compliance with the applicable safety regulatory requirements and with the procedural provisions of a Safety Management System if one is in place. They are intended to provide assurance of the safety management functions, including staffing, compliance with applicable regulations, levels of competency and training.

An audit may include one or more components of the total system, such assafety policy, change management, SMS as a whole, operating procedures, emergency procedures, etc. The aim is to disclose the strengths and weaknesses, to identify areas of non-tolerable risk and devise rectification measures. The outcome of the audit will be a report, followed by an action plan prepared by the audited organization and approved by the regulator/supervisory authority. The

Implementation of the agreed safety improvement measures shall be monitored by the supervisory authority.

Safety audits are used to ensure that:

□ Organisation's SMS has a sound structure and adequate staffing levels;

□ Approved procedures and instructions are complied with; the required level of personnel competency and training to operate equipment and facilities,

 \Box To maintain their levels of performance, is achieved;

□ Equipment performance is adequate for the safety levels of the service provided;

□ Effective arrangements exist for promoting safety, monitoring safety performance and processing safety issues;

15

 \Box Adequate arrangements exist to handle foreseeable emergencies.

Safety audits are carried out by a single individual or a team of people who arecompetent (adequately qualified, experienced and trained) and have a satisfactorydegree of independence from the audited organization or unit. The frequency of the audits depends on the regulatory/management policy. For example some Stateauthorities may conduct annual safety audits; others may consider that a full safetyaudit is only necessary at a few years interval.

Ad- hoc safety audits may be conducted to verify the compliance of a particular system component or activity, or may be initiated following an incident. Safety audits are one of the principal methods for fulfilling the safety performance monitoring requirements. Often audits are integrated, i.e. they include not only safety but also other business processes and performance areas, such as quality, capacity, cost efficiency etc.

All audits should be pre-planned and supporting documentation (usually in the form of checklists) of the audit content prepared. Among the first steps in planning an audit will be to verify the feasibility of the proposed schedule and to identify the information that will be needed before commencement of the audit. It will also be necessary to specify the criteria against which the audit will be conducted and to develop a detailed audit plan together with checklists to be used during the audit. The conduct of the actual audit is essentially a process of inspection or fact-finding. Information from almost any source may be reviewed as part of the audit.

The techniques for gathering the information include:

- \Box Review of documentation
- \Box Interviews with staff
- \Box Observations by the audit team

Responsibilities

- Management
- Design and schedule audit and inspection procedures for all work areas, processes and procedures.
- Conduct routine audits and inspections
- Ensure audits are conducted by employees who understand the various safety programs and policies

• Supervisors

- conduct informal daily safety inspections and ensure all unsafe conditions are corrected
- conduct documented weekly inspections and ensure all unsafe conditions are corrected

Corrections

- All safety deficiencies found during audits and inspections should be corrected as soon as possible. Documentation of corrections should be made on the audit or inspection sheet. And conditions that present a hazards are to be corrected or controlled immediately.
- Types of Inspections
- Supervisor & Management Daily Walk-through: this is an undocumented inspection that is made daily prior to startup and shift change to ensure the facility and equipment are in safe conditions for Employees. All noted unsafe areas are placed in a safe condition prior to Employees working in the area.
- Weekly Supervisor Inspections are conducted and recorded with a Employee. This documented inspection provides a focus to ensure current hazard controls are still effective, equipment is in safe condition and safe work practices are in use. Discrepancies are listed on the inspection sheet, recorded on work orders for correction. The inspection sheet is forwarded to the Safety Manager for review and logging to track discrepancy correction.
- Monthly Safety Committee Inspection. Each month members of the Safety Committee will tour the entire facility with the Safety Manager. This tour is to ensure Safety Committee Members are familiar with all areas of the operation. Record of problem areas, committee recommendations and deficiencies will be recorded and provided to management.
- Noise Surveys are conducted at least annually, or whenever facility modifications are made that impact the ambient or specific work area noise levels, Noise surveys are conducted by qualified persons with calibrated instruments.

Safety committee

Requirement for Safety and Health Committee

 \Box Prime contractors must establish a safety and health committee at a construction project site

where the total number of workers at the site is 20 or more, and the project is expected to require more than 90 days to complete.

□ All seasonal workplaces where 20 or more workers are expected to work for at least 90 days must have a safety and health committee.

□ The director of Workplace Safety and Health may designate the requirement for a safety and health committee at any workplace

Forming a Safety and Health Committee

□ Committees consist of no fewer than four or greater than 12 persons.

 \Box At least half of the committee members – the "worker members" – must represent workers who are not associated with the management of the workplace. The number of committee members representing management – the "employer members" – must not exceed those representing workers.

 \Box A committee shall have two co-chairs, one chosen by worker members and one chosen by employer members.

Democratic Elections

 \Box In a unionized workplace, the union(s) should select/elect worker members in accordance with their constitution.

 \Box In a non-unionized workplace, the employer must designate one or more workers not connected with management to co-ordinate the democratic election of worker members.

 \Box Term of office is two years. At term-end, members are eligible for re-election. For unionized workers, term of office is determined by the union constitution

No Employer or Worker Influence

 \Box No employer or worker shall attempt to influence the appointment or election of the other party's members.

Competently Trained Committee Members

 \Box Both worker and employer safety and health committee members must be competently trained to perform their duties. Competently trained committee members demonstrate an employer's commitment to workplace safety and health, and provide guidance to workers and employers on safety and health matters. Competent training includes knowledge of safety and health rights, roles and responsibilities as well as knowledge of any of the tasks that may be required of a safety and health representative

Assessing Committee Training Needs

Every workplace is unique. Training needs of safety and health committee members will vary from workplace to workplace.

For the Employer

 \Box Establish a written workplace safety and health program. See Section 7.4(1) of The Workplace Safety and Health Act, W210.

 \Box Send a copy of the committee minutes to Manitoba Workplace Safety and Health within seven days of receiving a copy.

□ Respond in writing to committee recommendations within 30 days, including short and long term control measures to address the recommendations.

□ Provide a bulletin board located in a prominent place for the exclusive use of committee members in connection with safety and health subjects.

□ Provide a meeting place for the committee during regular working hours.

□ Provide each committee member the greater of 16 hours or the number of hours theworker normally works during two shifts annually for safety and health educational leave(training seminars) to ensure competency.

 \Box Committee members must be paid for the greater of the hours spent at training or the regularly worked hours at a shift.

□ Consult and co-operate with the committee.

Advise the committee of the planned introduction of new equipment, new operating procedures, new chemicals or other new substances or materials.

 \Box Committee members are entitled to take time off from regular work duties in order to carry out the required duties of a committee member:

 $\sqrt{}$ One hour or more, as determined necessary by the committee to prepare for committee meetings.

 $\sqrt{1}$ Time required to attend each meeting.

 $\sqrt{1}$ Time required to attend safety and health training in accordance with The Workplace Safety and Health Act, Section 44, as approved by the employer.

 $\sqrt{1}$ Time required to carry out other assigned duties of a committee member.

 \Box Members shall be paid by the employer at regular or premium pay, as applicable, for all time spent carrying out the duties of a committee member.

Meeting Guidelines

Regularly Held Meetings

Meet regularly, at intervals determined by the committee, but not less than once every three months.

Quorum:Quorum is met when at least one half of the worker members and one half of the employer members of the committee are in attendance.

Three-Stage Procedure for Handling Concerns – No Imminent Risk

 \Box Stage One (Direct Resolution) – Supervisor shall attempt to resolve the matter, with involvement from a worker member of the committee where practicable, and, in certain circumstances, the affected worker. Concerns resolved in this manner shall be recorded in the minutes of the next meeting.

 \Box Stage Two (Committee Involvement) – Where a satisfactory resolution is not achieved at the first stage, the committee member or supervisor shall ensure the concern is on the agenda of the upcoming meeting for the purpose of resolution. The concern shall be placed on the agenda of each successive meeting until it is resolved.

 \Box Stage Three (Outside Assistance) – If the committee members are unable to resolve the concern, they shall request assistance from Manitoba Workplace Safety and Health (WSH), Department of Labour and Immigration. Committee members may also request assistance from other appropriate consultation services. It is preferable that all committee members agree when a request for assistance is made; however, such agreement is not required.

Duties and Responsibilities of Committee Members

 \Box Protect the anonymity of complainants when requested.

□ Notify complainants of any decisions or recommendations made by the committee relating to their concerns.

□ Periodically assist the employer with determining the types of hazards that may be encountered in the workplace.

 \Box On a regular basis, at least every 90 days, and prior to regular meetings, inspect the entire workplace and the operations conducted therein.

□ Participate in investigations of incidents and dangerous occurrences at the workplace.

□ Review safety of new equipment, materials or processes and make recommendations accordingly.

 $\hfill\square$ Worker co-chair or designate may be required to accompany a WSH Safety and Health Officer

during any inspection or investigation. They may be joined by the employer co-chair or designate.

 $\hfill\square$ Distribute and display safety and health information and educational materials relevant to your

workplace.

 \Box Ensure the safety and health committee minutes have been given to the employer.

 \Box If required, perform the duties of a worker co-chair (e.g., in their absence).

Duties and Responsibilities of Committee Co-chairs

 \Box Meeting chairpersonship alternates between the two co-chairs from meeting to meeting.

□ Co-chairs participate as equally as any other member in the discussions and decisions of the committee.

- □ Conduct investigations of serious incidents.
- □ Inspect dangerous conditions.
- □ May call special meetings to deal with matters of urgent concern.

Agenda

- \Box Co-chairs of the committee prepare the agenda.
- \Box Include the place and time of the meeting.
- □ Forward to individual committee members at least three clear days in advance.
- □ Post the agenda on the safety and health bulletin board in advance.
- □ Meeting discussion to focus only on safety and health issues.

Minutes

□ Use WSH form or create your own (must contain all fields in WSH form) to record minutes.

 \Box Put the name and address of your workplace in the minutes.

 \Box List those in attendance and their role (e.g., worker rep, employer rep, resource person).

- □ Record the date an issue was raised (use the "origin" column on the WSH form).
- \Box Minutes must be signed by both co-chairs.
- \Box Minutes must be kept for 10 years.
- □ Distribute minutes to workers within seven days.
- □ Put a copy in your safety and health committee files.
- □ Circulate minutes to safety and health committee members.
- \Box Post minutes on the workplace safety and health bulletin board.

□ Email minutes within seven days of meeting to WSH at cominutes@gov.mb.ca; or fax them to WSH at 948-2209; or mail minutes to:

The Safety and Health Bulletin Board

The safety and health bulletin board must be readily accessible to workers. Board to Include:

 \Box Names of all committee members, how to contact them and their term of office expiry date.

□ Scheduled dates (and times, when available) of committee meetings.

 \Box Meeting agenda – post ahead of time.

 \Box Meeting minutes – post within one week. Leave minutes up until at least one month after the next meeting has passed.

- □ Items recommended by committee members.
- □ Items/materials issued by WSH.



SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – I I– Industrial safety – SBT1609

HAZARDOUS WASTE CLASSIFICATION

The hazardous waste identification process and the definition of hazardous waste, and be familiar with the following concepts:

- hazardous waste listings
- hazardous waste characteristics
- the "mixture" and "derived-from" rules
- the "contained-in" policy

The RCRA regulations at 40 CFR §262.11 require that any person who produces or generates a waste must determine if that waste is hazardous. In doing so, §262.11 presents the steps in the hazardouswaste identification process:

- Is the waste a "solid waste"?
- Is the waste specifically excluded from the RCRA regulations?
- Is the waste a "listed" hazardous waste?
- Does the waste exhibit a characteristic of hazardous waste?

LISTED HAZARDOUS WASTES

EPA has studied and listed as hazardous hundreds of specific industrial wastestreams. These wastes are described or listed on four different lists that are found in the regulations at Part 261, Subpart D. These four lists are:

The F list — The F list designates particular solid wastes from certain common industrial or manufacturing processes as hazardous. Because the processes

producing these wastes can occur in different sectors of industry, the F list wastes

are known as wastes from nonspecific sources. The F list is codified in the

regulations at §261.31.

• The K list — The K list designates particular solid wastes from certain specific

industries as hazardous. K list wastes are known as wastes from specific sources.

The K list is found at §261.32.

• The P list and the U list — These two listsare similar in that both list pure or

commercial grade formulations of certain specific unused chemicals as hazardous.

Both the P list and U list are codified in §261.33.

These four lists each designate anywhere from 30 to a few hundred wastestreams as hazardous. Each waste on the lists is assigned a waste code consisting of the letter associated with the list followed by three numbers. For example, the wastes on the F list are assigned the waste codes

F001, F002, and so on. These waste codes are an important part of the RCRA regulatory system. Assigning the correct waste code to a waste has important implications for the management standards that apply to the waste.

EPA only uses these criteria when evaluating whether to list a waste; the listing criteria are not used by waste handlers, who refer to the actual hazardous waste lists for hazardous waste identification purposes. There are four different criteria upon which EPA may base its determination to list a waste as hazardous. These criteria are codified in Part 261, Subpart B. Note that these four criteria do not directly correspond to the four different lists of hazardous waste. The four criteria EPA may use to list a waste are:

• The waste typically contains harmful chemicals, and other factors indicate that it could pose a threat to human health and the environment in the absence of special regulation. Such wastes are known as toxic listed wastes.

• The waste contains such dangerous chemicals that it could pose threat to human health and the environment even whenproperly managed. Such wastes are known as acutely hazardous wastes.

• The waste typically exhibits one of the four characteristics of hazardous waste described in the hazardous waste identification regulations (ignitability, corrosivity, reactivity, or toxicity).

When EPA has to cause to believe for some other reason, the waste typically fits within the statutory definition of hazardous waste developed by Congress.

EPA assigns a hazard code to each waste listed on the F, K, P, and U lists. These hazard codes are listed below. The last four hazard codes apply to wastes that have been listed because they typically exhibit one of the four regulatory characteristics of hazardous waste. You will learn more about the four characteristics of hazardous waste. The hazard codes indicating the basis for listing a waste are:

Toxic Waste	(T)
Acute Hazard	(H)
Ignitable Waste (I)	(I)
Corrosive Waste	(C)
Reactive Waste (R)	(R)
Toxicity Characteristic Waste	(E)

THE F LIST: WASTES FROM NONSPECIFIC SOURCES

The F list designates as hazardous particular wastestreams from certain common industrial or manufacturing processes. F list wastes usually consist of chemicals that have been used for their intended purpose in an industrial process. That is why F list wastes are known as "manufacturing process wastes." The F list wastes can be divided into seven groups, depending on the type of manufacturing or industrial operation that creates them. The seven categories of F-listed wastes are:

• spent solvent wastes (F001 - F005)

• wastes from electroplating and other metal finishing operations (F006 - F012, F019)

• dioxin-bearing wastes (F020 - F023 and F026 - F028)

• wastes from the production of certain chlorinated aliphatic hydrocarbons (F024, F025)

- wastes from wood preserving (F032, F034, and F035)
- petroleum refinery wastewater treatment sludges (F037 and F038)
- multisource leachate (F039).
- Spent Solvent Wastes

Waste codes F001 - F005 apply to wastestreamsfrom the use of certain common organic solvents. Solvents are chemicals with many uses, although they are most often used in degreasing or cleaning. The solvents covered by the F listings are commonly used in industries ranging from mechanical repair to dry cleaning to electronics manufacturing. EPA decided that only certain solvents used in certain ways produce wastestreams that warrant a hazardous waste listing. Therefore, a number of key factors must be evaluated in order todetermine whether the F001 - F005 waste codes apply to a particular waste solvent. First, one or more of the 31 specific organic solvents designated in the F001 - F005 listing description must have been used in the operation that created the waste. Second, the listed solvent must have been used in a particular manner – it must have been used for its "solvent properties," as EPA defines that expression. Finally, EPA decided that only a wastestream created through use of concentrated solvents should be listed. Thus, the concentration of the solvent formulation or product before its use in the process that created the waste is alsoa factor in determining the applicability of the F001 - F005 listing.

Wastes from the Production of Certain Chlorinated Aliphatic Hydrocarbons

The F024 and F025 listings designate as hazardous certain wastestreams produced in the manufacture of chlorinated aliphatic hydrocarbons. These listings stand out on the F list (the list of wastes from nonspecific sources) because theyfocus on wastes from a very narrow industrial sector.

Wood Preserving Wastes

The F032, F034, and F035 listings apply to certain wastes from wood preserving operations. Many types of wood used for construction or other non-fuel applications is chemically treated to slow the deterioration caused by decay and insects. Such chemical treatment is commonly used in telephone poles, railroad ties, and other wood products prepared to withstand the rigors of outdoor use.

THE K LIST: WASTES FROM SPECIFIC SOURCES

The K list of hazardous wastes designates particular wastes from specific sectors of industry and manufacturing as hazardous. The K list wastes are therefore known as wastes from specific sources. Like F list wastes, K list wastes are manufacturing process wastes. They contain chemicals that have been used for their intended purpose. To determine whether a waste qualifies as K-listed, two primary questions must be answered. First, is the facility that created the waste within one of the industrial or manufacturing categories on the K list? Second, does the waste

match one of the specific K list waste descriptions? The 13 industries that can generate K list wastes are:

- wood preservation
- inorganic pigment manufacturing
- organic chemicals manufacturing
- inorganic chemicals manufacturing
- pesticides manufacturing
- explosives manufacturing
- petroleum refining
- iron and steel production
- primary aluminum production
- secondary lead processing
- veterinary pharmaceuticals manufacturing
- ink formulation
- coking (processing of coal to produce coke, a material used in iron and steel

production).

THE P AND U LISTS: DISCARDED COMMERCIAL CHEMICAL PRODUCTS

The P and U lists designate as hazardous pure or commercial grade formulations of certain unused chemicals. As you will see, the P and U listings are quite different from the F and K

listings. For a waste to qualify as P- or U-listed, a waste must meet the following three criteria:

- the waste must contain one of the chemicals listed on the P or U list
- the chemical in the waste must be unused
- the chemical in the waste must be in the form of a "commercial chemical product," as

EPA defines that term.

The following paragraphs explore these three criteria in detail and examine EPA's rationale in creating the P and U lists.

You have already learned that hazardous waste listings are narrative descriptions of specific

wastestreams and that a waste's actual chemical composition is generally irrelevant to whether a listing applies to it. At first glance, the P and U listings seem inconsistent with these principles. Each P and U listing consists only of the chemical name of a compound known to be toxic or otherwise dangerous; no description is included. EPA adopted this format because the same narrative description applies to all P and U list wastes. Instead of appearing next to each one of the hundreds of P and U list waste codes, this description is found in the regulatory text that introduces the two lists.

The generic P and U list waste description involves two key factors. First, a P or U listing applies only if one of the listed chemicals is discarded unused. Inother words, the P and U lists do not apply to manufacturing process wastes, asdo the F and K lists. The P and U listings apply to unused chemicals that become wastes. Unused chemicals become wastes for a number of reasons. For example, some unused chemicals are spilled by accident. Others are intentionally discarded because they are off-specification and cannot serve the purpose for which they were originally produced.

The second key factor governing the applicability of the P or U listingsis that the listed chemical must be discarded in the form of a "commercial chemical product."

CHARACTERISTIC HAZARDOUS WASTES

A hazardous waste characteristic is a property that indicates that a waste poses a sufficient threat to deserve regulation as hazardous. EPA tried to identify characteristics which, when present in a waste, can cause death or illness in humans orecological damage. EPA also decided that the presence of any characteristic of hazardous waste should be detectable by using a standardized test method or by applying general knowledge of the waste's properties. EPA believed that unless generators were provided with widely available and uncomplicatedtest methods for determining whether their wastes exhibited hazardous characteristics, this systemof identifying hazardous waste should be unfair and impractical. Given these criteria, EPA only finalized four hazardous waste characteristics. These characteristics are a necessary supplement to the hazardous waste listings. They provide a screening mechanism that waste handlers must apply to all wastes from all industries. In this sense, the characteristics provide a more complete and inclusive means of identifying hazardous wastes than do the hazardouswaste listings. The four characteristics of hazardous waste are:

ignitability

- corrosivity
- reactivity
- toxicity.

GNITABILITY

Ignitable wastes are wastes that can readily catch fire and sustain combustion. Many paints, cleaners, and other industrial wastes pose such a fire hazard. Most ignitable wastes are liquid in physical form. EPA selected a flash point testas the method for determining whether a liquid waste is combustible enough to deserve regulation ashazardous. The flash point test determines the lowest temperature at which a chemical ignites when exposed to flame. Many wastes in solid or nonliquid physical form (e.g., wood, paper) can also readily catch fire and sustain combustion, but EPA did not intend to regulate most of these nonliquid materials as ignitable wastes.

CORROSIVITY

Corrosive wastes are acidic or alkaline (basic) wastes which can readily corrode or dissolve flesh, metal, or other materials. They are also among the most common hazardous wastestreams. Waste sulfuric acid from automotive batteries is an example of a corrosive waste. EPA uses two criteria to identify corrosive hazardous wastes. The first is a pH test. Aqueous wastes with a pH greater than or equal to12.5, or less than or equal to 2 are corrosive under EPA's rules. A waste may also be corrosive if it has the ability tocorrode steel in a specific EPA-approved test protocol. Corrosive wastes carry the waste code D002. The regulations describing the corrosivity characteristic are found at §261.22

REACTIVITY

A reactive waste is one that readily explodes or undergoes violent reactions. Common examples are discarded munitions or explosives. In many cases, there is no reliable test method to evaluate a waste's potential to explode or react violentlyunder common handling conditions. Therefore, EPA uses narrative criteria to define most reactive wastes and allows waste handlers to use their best judgment in determining if a waste is sufficiently reactive to be regulated. This is possible because reactive hazardous wastes are relatively uncommon and the dangers they pose are well known to the few waste handlers who deal with them. A waste is reactive if it meets any of the following criteria:

- it can explode or violently react when exposed to water, when heated, or under normal handling conditionsit can create toxic fumes or gases when exposed to water or undernormal handling conditions
- it meets the criteria for classification as an explosive under Department of Transportation rules
- it generates toxic levels of sulfide or cyanide gas when exposed to a pH range of 2 through 12.5.

COLLECTION OF HAZARDOUS WASTE



Solid waste collection shall be required by all residential dwelling units. It shall be the responsibility of the owner or occupant of any residential dwelling unit to apply for solid waste collection services. The city public works department, sanitation collection division, shall be the sole, exclusive solid waste collection service for all residential dwelling units, including but not limited to single-family dwellings, multiple-family dwellings, townhouses, apartment complexes and trailer parks. Collection of household solid waste generated at a residential dwelling unit by a solid waste collector other than the city public works department, sanitation collection division must be approved through a formal agreement between the city and the solid waste collector. Collection and hauling of household hazardous waste, white goods, recyclables and other solid wastes which are not household solid waste shall be the responsibility of the residential dwelling unit owner or occupant.

(2) Owners or occupants of residential dwelling units may haul and deliver to the municipal landfill household solid waste generated from their residential dwelling unit; however, such hauling and delivery shall not reduce the solid waste collection fees owed to the city.

(3) Commercial accounts may use their own equipment and their own employees to collect and haul solid waste generated by the business to the municipal landfill or contract solid waste collection services to the city of Ketchikan public works department, sanitation collection division. Collection of commercial solid waste by a solid waste collector other than the city public works department, sanitation collection division must be approved through a formal agreement between the city and the solid waste collector.

(4) Collection Schedule.

(A) All solid waste shall be collected and disposed of at intervals determined by the director of public works or his designee.

(B) Residential dwelling units shall have a minimum of weekly service unless otherwise determined by the director of public works or his designee.

(C) Cafes, restaurants and other establishments serving food; commercial business; industrial businesses, and all other establishments shall have a level of service that does not create a public nuisance or health hazard as determined by the director of public works or his designee.

(c) Solid Waste Collection Fees.

(1) Solid Waste Collection Fee for Residential Accounts. All residential accounts will be assessed and charged a solid waste collection fee of \$10.69 per month for the collection of household solid waste. The owner of the residential dwelling unit shall be responsible for solid waste collection fees which are not paid by the occupant.

(2) Solid Waste Collection Fee for Commercial Accounts. Unless otherwise negotiated and agreed to by the city, commercial accounts for which the city provides solid waste collection services shall be charged the following fees or \$28.69 per month, whichever is greater.

Collection

Collection simply refers to how waste is collected for transportation to the final disposal site. Any collection system should be carefully planned to ensure that storage facilities do not become overloaded. Collection intervals and volumes of collected waste must be estimated carefully.

Transportation

This is the stage when solid waste is transported to the final disposal site (see 7.6 for more details). There are various modes of transport which may be adopted and the chosen method depends upon local availability and the volume of waste to be transported. Types of transportation can be divided into three categories

- Human-powered: open hand-cart, hand-cart with bins, wheelbarrow, tricycle
- Animal-powered:donkey-drawn cart
- Motorised: tractor and trailer, standard truck, tipper-truck



TREATMENT OF HAZARDOUS WASTE

Disinf ectant the waste so that it is no longer a source of pathogenic organisms.

Reduce the bulk in order to reduce requirement f or storage and transportation.

Make the waste unrecognisable f or aesthetic reasons

Make recyclable items unusable, for example, cutting up syringes and damage the needles.

Recycling infectious plastic waste can be considered only after adequate disinf ection/sterilization.

Disposal items, such as gloves, syringes, and the like, should be mutilated after use to prevent illegal packing and reuse.

Code coding of bags should be done as per regulation.

□Needles, syringes and other sharp instruments and objects should be placed in a puncture–resistant plastic/ metal container at the workstation.

 \Box Alternatively, sharp waste may be transported to a central site f or treatment and container may be reused, but after cleaning and disinf ecting.

 $\hfill\square$ 50% of needle stick injuries are as a result of reheating. Therefore, do not recap the waste.

Chemical disinf ectant prior to disposal is required for sharp, disposal infectious plastic/rubber, and infectious glassware and blood fluids by 1% hypochlorite or equivalent disinf ectant. Always ensure that the right concentration of the disinfectant is used.

Incineration

The combustible elements of both radioactive and other wastes can be incinerated^a to reduce volume. The incineration of many kinds of hazardous waste (*e.g.* waste oils, solvents) and non-hazardous waste (municipal waste, biomass, tyres, sewage sludge) is practised in many countries, subject to emission limits.

In the case of radioactive waste, it has been used for the treatment of LLW from nuclear power plants, fuel production facilities, research centres (such as biomedical research), the medical sector, and waste treatment facilities.

Following the separation of non-combustible constituents, the waste is incinerated in a specially engineered kiln at temperatures up to around 1000°C. The gases and fumes produced during incineration are treated and filtered prior to emission into the atmosphere, and emissions must conform to international standards and national regulations. After incineration, the resulting ash, which contains the radionuclides, may require further conditioning, such as cementation or bituminisation, prior to disposal. Compaction may also be used to further reduce the volume, if this is deemed to be cost-effective. Overall volume reduction factors of up to around 100 are achieved, primarily for LLW, depending on the density of the waste

VITRIFICATION

Vitrification is a process used to stabilize and encapsulate high-level **radioactive waste**. In the **vitrification** process, **radioactive waste** is mixed with a substance that will crystallize when heated (e.g., sugar, sand) and then calcined. ... **Vitrification** allows the immobilization of the **waste** for thousands of years.

The immobilisation of HLW requires the formation of an insoluble, solid waste form that will remain stable for many thousands of years. In general borosilicate glass has been chosen as the medium for dealing with separated HLW. The stability of ancient glass for thousands of years highlights the suitability of borosilicate glass as a matrix material. This type of process, referred to as vitrificationd, has also been extended for lower level wastes where the type of waste or the

economics have been appropriate.Most HLW, other than spent fuel itself, arises in a liquid form from the reprocessing of spent fuel. This HLW comprises highly-radioactive fission products and some transuranic elements with long-lived radioactivity. To allow incorporation into the glass matrix the waste is initially calcined (dried) to a granular powder. The product is then incorporated into molten glass, poured into a robust stainless steel canister about 1.3 metres high, and allowed to cool, forming a solid matrix. The containers are then welded closed and are ready for storage and final disposal. This process is currently being used in France, Japan, Russia, UK, and USA and is seen as a suitable and adequate process for management of separated HLW arising from reprocessing. The capacity of western European vitrification plants is about 2,500 canisters (1000 t) a year, and some have been operating for three decades.In-situ vitrification has also been investigated as a means of 'fixing' activity in contaminated ground as well as creating a barrier to prevent further spread of contamination.

Disposal

The final stage of solid waste management is safe disposal where associated risks are minimised. There are four main methods for the disposal of solid waste:

- Land application: burial or landfilling
- Compositing
- Burning or incineration

LAND FILLING

Once solid waste is transported off-site it is normally taken to a landfill site. Here the waste is placed in a large excavation (pit or trench) in the ground, which is back-filled with excavated soil each day waste is tipped. Ideally, about 0.5m of soil should cover the deposited refuse at the end of each day to prevent animals from digging up the waste and flies from breeding.

The location of landfill sites should be decided upon through consultation with the local authorities and the affected population. Sites should preferably be fenced, and at least one kilometre downwind of the nearest dwellings.

Advantages: A sanitary disposal method if managed effectively.

Constraints: A reasonably large area is required

Incineration

Although burning or incineration is often used for the disposal of combustible waste, this should generally only take place off-site or a considerable distance downwind of dwellings. Burning refuse within dwelling areas may create a significant smoke or fire hazard, espe- cially if several fires are lit simultaneously. Burning may be used to reduce the volume of waste and may be appropriate where there is limited space for burial or landfill. Waste should be ignited within pits

and covered with soil once incinerated, in the same manner as landfilling. The same constraints for siting landfill sites should be applied here also.

Advantages: Burning reduces volume of combustible waste considerably; and it is appropri- ate in off-site pits to reduce scavenging.

Constraints: There can be smoke or fire hazards.

Composting

Simple composting of vegetables and other organic waste can be applied in many situations. Where people have their own gardens or vegetable plots, organic waste can be dug into the soil to add humus and fibre. This makes the waste perfectly safe and also assists the growing process. This should be encouraged wherever possible, particularly in the later stages of an emergency programme.

Properly managed composting requires careful monitoring of decomposing waste to controlmoisture and chemical levels and promote microbial activity. This is designed to produce compost which is safe to handle and which acts as a good fertiliser. Such systems require considerable knowledge and experience and are best managed centrally. In general, they are unlikely to be appropriate in emergencies.

Advantages: Composting is environmentally friendly; and beneficial for crops.

Constraints: Intensive management and experienced personnel are required for large-scale operations.

Recycling

Complex recycling systems are unlikely to be appropriate but the recycling of some waste items may be possible on occasions. Plastic bags, containers, tins and glass will often be automatically recycled since they are likely to be scarce commodities in many situations. In most developing country contexts there exists a strong tradition of recycling leading to lower volumes of waste than in many more developed societies.

Advantages: Recycling is environmentally friendly.

Constraints: There is limited potential in most emergency situations; and it is expensive to set up.

Protective measures

In order to minimise disease transmission there are several protective measures that can be undertaken. These concern equipment for staff and the siting and management of disposal sites.

Staff

It is important that workers employed to collect and transport solid waste are provided with appropriate clothing and equipment. Gloves, boots and overalls should be provided wherever possible. Where waste is burned, or is very dusty, workers should have protective masks. Water and soap should be available for hand and face washing, and changing facilities should be provided where appropriate.

Siting of disposal sites

The location of all disposal sites should be determined through consultation with key stakeholders including local government officials, representatives of local and displaced populations, and other agencies working in the area. Appropriate siting should minimise the effects of odour, smoke, water pollution, insect vectors and animals.

On-site disposal is generally preferred since this requires no transportation and staff needs are low. This is appropriate where volumes of waste are relatively small, plenty of space is available and waste is largely organic or recyclable.

If the volumes of waste generated are large, or space within the site is severely limited, it may be necessary to dispose of waste off-site. Where off-site disposal is to be used the following measures should be taken in selecting and developing an appropriate site:

- Locate sites at least 500m (ideally 1 kilometre) downwind of nearest settlement.
- Locate sites downhill from groundwater sources.
- Locate sites at least 50m from surface water sources.
- \Box Provide a drainage ditch downhill of landfill site on sloping land.
- Fence and secure access to site.



SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – III– Industrial safety – SBT1609

Biohazard agents

Biological hazards, also known as biohazards, refer to biological substances that pose a threat to the health of living organisms, primarily that of humans. It refers to organisms or organic matters produced by these organisms that are harmful to human health. These include parasites, viruses, bacteria, fungi and protein.

Levels of Biohazard

The United States Centers for Disease Control and Prevention (CDC) categorizes various diseases in levels of biohazard, Level 1 being minimum risk and Level 4 being extreme risk. Biohazard Level 1: Bacteria and viruses including Bacillus subtilis, canine hepatitis, Escherichia coli, varicella (chicken pox), as well as some cell cultures and non-infectious bacteria. At this level precautions against the biohazardous materials in question are minimal, most likely involving gloves and some sort of facial protection.

Biohazard Level 2: Bacteria and viruses that cause only mild disease to humans, or are difficult to contract via aerosol in a lab setting, such as hepatitis A, B, and C, some influenza A strains, salmonella, mumps, measles, scrapie, dengue fever.

Biohazard Level 3: Bacteria and viruses that can cause severe to fatal disease in humans, but for which vaccines or other treatments exist, such as anthrax, West Nile virus, SARS virus, MERS coronavirus, tuberculosis,typhus, Rift Valley fever, Rocky Mountain spotted fever, yellow fever, and malaria. Among parasites *Plasmodium falciparum*, which causes Malaria, and *Trypanosoma cruzi*, which causes trypanosomiasis, also come under this level.

Biohazard Level 4: Viruses and bacteria that cause severe to fatal disease in humans, and for which vaccines or other treatments are not available, such as Bolivian and Argentine hemorrhagic fevers, Marburg virus, Ebola virus, Lassa fever virus, Crimean–Congo hemorrhagic fever, and other hemorrhagic diseases.

Employee Health Program

healthcare facility must establish an employee health care program to ensure the wellbeing and safety of all workers in the institution and protect patients from contracting communicable infections from the healthcare workers.

Administrative procedures:

a. The employee health program is supervised by the occupational health directorate.

b. Each healthcare institution must dedicate a suitable space for an Employee Health
Clinic. The clinic is administratively under the medical director of the hospital or the medical director of the outpatient department.

c. During off-duty hours, weekends and national holidays, the emergency medical services department will be responsible for employee health matters that need urgent attention (e.g. post-exposure management of sharps and needle stick injuries, evaluating and treating work related injuries).

d. The clinic staffing should be the following:

i. Physician, preferably with experience or certification in occupational or public health or family medicine.

ii. Nurse, preferably with experience or certification in occupational or public health.

iii. Clerk.

iv. Information technologist (IT).

e. Clinic equipment:

i. Specific space in outpatient clinic department.

ii. Equipped with examination and treatment requirements (purified protein derivative (PPD), injections, etc.).

iii. Desktop and internet connection for data entry (Epinet, Health Electronic

Surveillance Network (HESN).

iv. Software for data entry and saving.

v. Clinical examination room supplied with:

1. Examination table and chair.

- 2. Ladder for the patient.
- 3. Desk for the physician and chair for the patient.
- 4. Hand washing basin and alcohol-based hand rub dispenser.
- 5. Cupboard for saving supplies.
- 6. Vaccination refrigerator.
- 7. Bedside table for patient equipment.
- 8. Bedside light source.
- 9. Sphygmomanometer, pulse counter, medical thermometer and device
- for measuring arterial blood gas levels.
- 10. Desktop for the physician.
- 11. Administrative room for the administrative clerk equipped with:
- a. Desks for the clerk and nurses.
- b. Two computers, a printer, a fax, a scanner, and a photocopy machine.
- c. Cupboard for keeping stuff medical files.
- d. Files, papers, pens and pencils, etc.
- f. The clinic will generate reports on the following:
- I. Reportable infections in the HCW as per public health policy.
- II. Sero-conversion rates Hepatitis B (HB), Hepatitis C virus (HCV),
- Human Immunodeficiency Virus (HIV).
- III. PPD/IGRA conversion rates.
- IV. Needle stick injuries.
- V. Work related injuries and illnesses.

Scope of service:

The employee health program will perform the following duties through Employee Health

Clinic (EHC):

i. Record keeping.

ii. Medical and Occupational history.

iii. Pre-employment screening.

iv. Periodic medical examinations (and follow-up examinations when appropriate).

v. Vaccination according to most recent and updated international standards.

vi. Management of needle stick injuries and body fluids exposures.

vii. Post exposure prophylaxis, follow up and treatment in cases of incidents.

viii. In case of incident with potential transmission of infectious disease, the case should be referred to the infectious diseases department in the institution.

ix. Management of work-related injuries and occupational illnesses, and referral as needed.

x. Referral in case of usual non-emergency cases and chronic diseases.

xi. Applying work restriction rules according to international references.

xii. Training.

xiii. Occupational health risk management.

xiv. Investigation or participation in the investigation of occupational incidents.

xv. Treatment, rehabilitation and compensation services.

05.3 Record-keeping:

Each employee should have a medical file. The employee health program will create a medical file for each HCW. The files are kept confidential in a secure place and separate

from the hospital patient's files. The HCW file contain the following:

- a. HCW bio-data.
- b. Initial medical history and examination.
- c. Occupational history.
- d. Vaccination record.
- e. Results of all investigations.

Medical and Occupational History:

A. The employee health program will perform and record a pre-employment health assessment for all newly hired healthcare workers. The pre-employment assessment include but not limited to the following elements:

- 1. Complete medical history and physical examination.
- 2. Complete occupational history.
- 3. Vaccination history.
- 4. Investigations:
- i. Chest X-ray, complete blood count (CBC), liver and renal function tests.
- ii. HBV, HCV, and HIV screening.

iii. If vaccinated against HBV, a HBsAb titer should be performed.

iv. If vaccinated or has previous natural infection with Measles, Mumps, Rubella or Varicella, a document of the presence of protective serum IgG against those infections is mandatory.

v. A purified protein derivative (PPD) (2 step) skin test for tuberculosis or Interferon-gamma release assay (IGRA) - Assure employees of confidentiality.

B. Make sure the worker fills out an occupational and medical history questionnaire.

C. Review past illnesses and chronic diseases, particularly atopic diseases such as eczema and asthma, lung diseases, and cardiovascular disease.

D. Review symptoms, especially shortness of breath or labored breathing on exertion, other chronic respiratory symptoms, chest pain, high blood pressure.

E. Identify individuals who are vulnerable to particular exposures (e.g. surgeons, gynecologists and obstetricians, anesthesiologists, and technicians, laboratory and blood bank workers exposed to blood and other body fluids, radiologists and technicians exposed to radiations, etc.)

Laboratory safety program



Having a strong set of overall laboratory safety rules is essential to avoiding disasters in the lab. *Lab Manager* recently scoured the safety policies of several laboratories to determine some of the most common lab safety rules out there, to help you whether you're developing or updating a set of policies for your own lab. Of course, safety rules are only effective when they are enforced, which is why strong lab management is so important to a safe laboratory as well. Knowing the proper <u>laboratory safety signs and symbols</u> is also important.

Here are the safety rules that most commonly came up in our look at several laboratories' policies:

General lab safety rules

The following are rules that relate to almost every laboratory and should be included in most safety policies. They cover what you should know in the event of an emergency, proper signage, safety equipment, safely using laboratory equipment, and basic common-sense rules.

- 1. Be sure to read all fire alarm and safety signs and follow the instructions in the event of an accident or emergency.
- 2. Ensure you are fully aware of your facility's/building's evacuation procedures.

- 3. Make sure you know where your lab's safety equipment—including first aid kit(s), fire extinguishers, eye wash stations, and safety showers—is located and how to properly use it.
- 4. Know emergency phone numbers to use to call for help in case of an emergency.
- 5. Lab areas containing carcinogens, radioisotopes, biohazards, and lasers should be properly marked with the appropriate warning signs.
- 6. Open flames should never be used in the laboratory unless you have permission from a qualified supervisor.
- 7. Make sure you are aware of where your lab's exits and fire alarms are located.
- 8. An area of 36" diameter must be kept clear at all times around all fire sprinkler heads.
- 9. If there is a fire drill, be sure to turn off all electrical equipment and close all containers.
- 10. Always work in properly-ventilated areas.
- 11. Do not chew gum, drink, or eat while working in the lab.
- 12. Laboratory glassware should never be utilized as food or beverage containers.
- 13. Each time you use glassware, be sure to check it for chips and cracks. Notify your lab supervisor of any damaged glassware so it can be properly disposed of.
- 14. Never use lab equipment that you are not approved or trained by your supervisor to operate.
- 15. If an instrument or piece of equipment fails during use, or isn't operating properly, report the issue to a technician right away. Never try to repair an equipment problem on your own.
- 16. If you are the last person to leave the lab, make sure to lock all the doors and turn off all ignition sources.
- 17. Do not work alone in the lab.
- 18. Never leave an ongoing experiment unattended.
- 19. Never lift any glassware, solutions, or other types of apparatus above eye level.
- 20. Never smell or taste chemicals.
- 21. Do not pipette by mouth.
- 22. Make sure you always follow the proper procedures for disposing lab waste.

- 23. Report all injuries, accidents, and broken equipment or glass right away, even if the incident seems small or unimportant.
- 24. If you have been injured, yell out immediately and as loud as you can to ensure you get help.
- 25. In the event of a chemical splashing into your eye(s) or on your skin, immediately flush the affected area(s) with running water for at least 20 minutes.
- 26. If you notice any unsafe conditions in the lab, let your supervisor know as soon as possible.

Housekeeping safety rules



Laboratory housekeeping rules also apply to most facilities and deal with the basic upkeep, tidiness, and maintenance of a safe laboratory.

- 1. Always keep your work area(s) tidy and clean.
- 2. Make sure that all eye wash stations, emergency showers, fire extinguishers, and exits are always unobstructed and accessible.
- 3. Only materials you require for your work should be kept in your work area. Everything else should be stored safely out of the way.
- 4. Only lightweight items should be stored on top of cabinets; heavier items should always be kept at the bottom.
- 5. Solids should always be kept out of the laboratory sink.
- 6. Any equipment that requires air flow or ventilation to prevent overheating should always be kept clear.

Dress code safety rules



As you'd expect, laboratory dress codes set a clear policy for the clothing employees should avoid wearing in order to prevent accidents or injuries in the lab. For example skirts and shorts might be nice for enjoying the warm weather outside, but quickly become a liability in the lab where skin can be exposed to heat or dangerous chemicals.

- 1. Always tie back hair that is chin-length or longer.
- 2. Make sure that loose clothing or dangling jewelry is secured, or avoid wearing it in the first place.
- 3. Never wear sandals or other open-toed shoes in the lab. Footwear should always cover the foot completely.
- 4. Never wear shorts or skirts in the lab.
- 5. When working with Bunsen burners, lighted splints, matches, etc., acrylic nails are not allowed.

Personal protection safety rules



Unlike laboratory dress code policies, rules for personal protection cover what employees *should* be wearing in the lab in order to protect themselves from various hazards, as well as basic hygiene rules to follow to avoid any sort of contamination.

- 1. When working with equipment, hazardous materials, glassware, heat, and/or chemicals, always wear face shields or safety glasses.
- 2. When handling any toxic or hazardous agent, always wear the appropriate gloves.
- 3. When performing laboratory experiments, you should always wear a smock or lab coat.

- 4. Before leaving the lab or eating, always wash your hands.
- 5. After performing an experiment, you should always wash your hands with soap and water.
- 6. When using lab equipment and chemicals, be sure to keep your hands away from your body, mouth, eyes, and face.

Chemical safety rules



Since almost every lab uses chemicals of some sort, chemical safety rules are a must. Following these policies helps employees avoid spills and other accidents, as well as damage to the environment outside of the lab. These rules also set a clear procedure for employees to follow in the event that a spill does occur, in order to ensure it is cleaned up properly and injuries are avoided.

- 1. Every chemical should be treated as though it were dangerous.
- 2. Do not allow any solvent to come into contact with your skin.
- 3. All chemicals should always be clearly labeled with the name of the substance, its concentration, the date it was received, and the name of the person responsible for it.
- 4. Before removing any of the contents from a chemical bottle, read the label twice.
- 5. Never take more chemicals from a bottle than you need for your work.
- 6. Do not put unused chemicals back into their original container.
- 7. Chemicals or other materials should never be taken out of the laboratory.
- 8. Chemicals should never be mixed in sink drains.
- 9. Flammable and volatile chemicals should only be used in a fume hood.
- 10. If a chemical spill occurs, clean it up right away.

11. Ensure that all chemical waste is disposed of properly.

Chemistry lab safety rules

As chemistry labs are one of the most common types, these basic chemistry lab safety rules are relevant to many scientists, dealing with the safe performance of common activities and tasks in the average chemistry lab:

- 1. Before you start an experiment, make sure you are fully aware of the hazards of the materials you'll be using.
- 2. When refluxing, distilling, or transferring volatile liquids, always exercise extreme caution.
- 3. Always pour chemicals from large containers to smaller ones.
- 4. Never pour chemicals that have been used back into the stock container.
- 5. Never tap flasks that are under vacuum.
- 6. Chemicals should never be mixed, measured, or heated in front of your face.
- 7. Water should not be poured into concentrated acid. Instead, pour acid slowly into water while stirring constantly. In many cases, mixing acid with water is exothermic.

Electrical safety rules



Like almost every other workplace, laboratories contain electronic equipment. Electrical safety rules help prevent the misuse of electronic instruments, electric shocks and other injuries, and ensure that any damaged equipment, cords, or plugs are reported to the appropriate authorities so they can be repaired or replaced.

- 1. Before using any high voltage equipment (voltages above 50Vrms ac and 50V dc), make sure you get permission from your lab supervisor.
- 2. High voltage equipment should never be changed or modified in any way.
- 3. Always turn off a high voltage power supply when you are attaching it.

- 4. Use only one hand if you need to adjust any high voltage equipment. It's safest to place your other hand either behind your back or in a pocket.
- 5. Make sure all electrical panels are unobstructed and easily accessible.
- 6. Whenever you can, avoid using extension cords.

Laser safety rules



Perhaps not as common as some of the other laboratory safety rules listed here, many laboratories do use lasers and it's important to follow some key rules of thumb to prevent injuries. In particular, accidents due to reflection are something that many employees may not think about. A clear set of rules for the use of lasers is essential to ensure that everyone is aware of all hazards and that the appropriate personal protective equipment is worn at all times.

- 1. Even if you are certain that a laser beam is "eye" safe or low power, you should never look into it.
- 2. Always wear the appropriate goggles in areas of the lab where lasers are present. The most common laser injuries are those caused by scattered laser light reflecting either off the shiny surface of optical tables, the sides of mirrors, or off of mountings. Goggles will help you avoid damage from such scattered light.
- 3. You should never keep your head at the same level as the laser beam.
- 4. Always keep the laser beam at or below chest level.
- 5. Laser beams should never be allowed to spread into the lab. Beam stops should always be used to intercept laser beams.
- 6. Do not walk through laser beams.

Biosafety Cabinets

BSCs are designed to provide personnel, environmental and product protection when appropriate practices and procedures are followed. Three kinds of biological safety cabinets, designated as Class I, II and III have been developed to meet varying research and clinical needs. High efficiency particulate air (HEPA) fil ters or ul tra-low penetration air (ULPA) filter s are used i n the exhaust and/or supply systems of biological safety cabinets.

HEPA Filters

Control of airborne particulate materials became possible with the development of filters which would efficiently remove microscopic contaminants from the air. The high efficiency particulate air (HEPA) filter was dev eloped to create dust-free work environments (e. g., "clean rooms" and "clean benches") in the 1940's.HEPA filters are generally rated as being effective at removing 0.3µm-sized particles with an efficiency of at least 99.97%; they are even more effective at removing both smaller and larger particles. The medium of a typical HEPA filter r is a single sheet of borosilicate fibers which has been treated with a wet-strength water-repellant binder. The filter medium is pleated to increase the overall surface area inside the filter frame , and the pleats are often divided by corrugated aluminum separators. The filter is glued into a wood, metal, or plastic frame. Careless handling of the filter (e. g., improper storage or dropping) can damage the medium at the glue joint and cause tears or shifting of the filter which result in leaks in the medium. This is the primary reason why filter integrity must be certified after a BSC is initially installed and after it has been relocated.

Class I BSC

The Class I BSC provides personnel and environmental protection, but no pro duct protection. It is similar in air movement to a chemical fume hood, but has a HEPA filter in the exhaust system to protect the environment. In theClass I BSC, unfiltered room air is drawn across the work surface. Personnel protection is provided by this inward airflow as long as a minimum velocity of 75 linear feet per minute (lfpm) is maintained through the front opening. Because of the productprotection provided by the Class II BSCs, general usage of the ClassI BSC has declined. However, in many cases ClassI BSCs are used specifical ly to enclose equipment (e.g., centrifuges, harvesting equipment or small fermenters), or procedures (e.g. cage dumping, aerating cultures or homogenizing tissues) with a

potential to generate aerosols that may flow back into the room .

The Class I BSC is hard-ducted to the building exhaustsystem, thimble-connected, orrecirc ulated backinto the room depending on use. If it is hard-ducted, t he building exhaust fan provides the staticpressure necessary to draw room air into the cabinet. Cabinet air is drawn through a HEPA filter as it enters the exhaust plenum. Sometimes a second HEPA filter is installed in the building exhaust system.

Class II BSC

As biomedical researchers began to use sterile animal tissue and cell cul ture systems, p articularly forthe propagation of viruses, cabinets were needed that also provided productprotection. In the ear ly 1960's, a principle evolved stating that unidirectional air moving at a steady velocity along parallel lines (i.e., "laminar flow") would aid in the capture and removal of airborne contaminants. Biocontainment technology also in corporated this laminar flow principle with the use of the HEPA filter to provide a particulate-free work environment. This combination serves to protect the laboratorian from the potentially infectious microorganisms being manipulated and provide necessary product protection.

The ClassII (Types A, B1, B2,and B3)biological safety cabinets provide personnel, environmental and product protection. Air flow is drawn around the operator into the front grille of the cabinet, which provides personnel protection. In addition, the downward laminar flow of HEPA-filtered air provides product protection by minimizing the chance of cross-contamination along the work surface of the cabinet. Because cabinet air exhaust is passed through a certified exhaust HEPA filter, it is contaminant free (environmental protection), and may be recirculated back into the laboratory (Type A BSC) or exhausted out of the building (Type B BSC). HEPA filtersare effective at trapping particulates and infectious agents, but not at capturing volatile chemicals or gases. All Class II cabi nets are designed for work involving microorganisms assigned to biosafety levels 1,2 and 3.

1. The Class II, Type A BSC-

An internal blower draws sufficient room air through the front grille to maintain a minimum calculated or measured average inflow velocity of at least 75 lfpm at the f ace op ening o f the ca binet. The su pply air lows through a HEPA filter and provides particulate-free air to the work su rface. Laminar airflow reduces turbulence in the work zone and minimizes the poten tial for cross-contamination. An unducted ClassII Type A BSC is not to be used for working volatile or toxic chemicals. The buildup of chemical vapor s in the cabinet (by recirculated air) and in the laboratory (from exhaust air) could create health and safety hazards.

2. The Class II, Type B1 BSC-

Some biomedical research requires the use of small quantities of certain Hazardous chemicals, such as carcinogens. The powdered form of these carcinogens should be weighed or manipulated ina chemical fume hood or a static-air glove box equipped with a double-door airlock.. Carcinogens used in cell culture or microbial systems require both biological and chemical containment.

3. The Class II, Type B2 BSC-

This BSC is a total exhaust cabinet; no air is recirculated within it This cabinet provides simultaneous primary biological and chemical containment. Consideration must be given to the chemicals used

in B SCs as some chemicals can destroy the filter medium, housings and /or gas kets ca using loss of containment. The supply blower draws in room air or outside air at the top of the cabinet, passes it through a HEPA fil ter and down int o the work area of the cabinet. The building or cabinet exhaust sy stem draws air through both the rear and front grills, capturing the supply air plus the additional amount of room air needed to produce a minimum

calculated or measured inflow face velocity of 100 lfpm . All air entering this cabinet is exhausted, and passes through a HEPA filter (and perhaps some other air-cleaning device such as a carbon filter) prior to discharge to the outside. Exhausting as much as 1200 cubic feet per minute of

conditioned room air makes this cabinet expensive to operate.

The Class II, Type B3 BSC- This biological safety cabinet (Fi gure 7) is an exhausted Type A cabinet having a minimum inward airflow of 100 lfpm . All positive pressure

contaminated plenums within the cabinet are surrounded by a negative air pressure plenum. Thus, leakage from a contaminated plenum will be into the cabinet and not into the environment.

Class III BSC

The Class III biological safety cabinet was designed for work with microbiological agents assigned to biosafety level 4, and provides maximum protection to the environment and the worker . It is a gas-tight (1x10-5 cc/sec leak rate) enclosure with a non-opening view window. Access for passage of materials into the cabinet is through a dunk tank (t hat is accessible through the cabinet floor) or double-door pass-through box (such as an autoclave) that can be decontaminated between uses. Reversing that process allows for safe removal of materials from the Class III biosafety cabinet. Both supply and exhaust air are HEPA filtered. Exhaust air must pass through two HEPA filters, or a HEPA filter and an air incinerator, before discharge to the outdoors . Airflow is maintained by a dedicated independent exhaust system exterior to the cabinet, which keeps the cabinet under negative pressure (usually about 0.5 inches of water gauge).

Development of Containment Standards

The evolution of containment equipment for varied research and diagnostic applications created the need forconsistency in construction, certification and performance. A Federal standard was developed to establish classes of air cleanliness and methods for monitoring clean work stat ions and clean rooms where HEPA filters ar e used to contr ol airborne particulates. The first"standard to be develop ed specifi cally for BSCs served as a Federal procurement spec ification for the NIH Class II, Type 1 (now called Type A) biological safety cabinet, which had a fixed or hinged front window or a vertical slidings ash, vertical downward laminar airflow and HEPA-filtered air supply and exhaust. This guideline specified design criteri a and defined prototype tests for microbiological aerosol challenge, velocity profiles, and leak testing of the HEPA filters. A similar procurement specification was generated when the Class II Type 2 (now called Type B1) cabinet was developed.

Standard No. 49 pertains to all models of Class II cabinets (Type A, B1, B2, and B3) and listsa series of specifications regarding:

- design/construction,
- performance,
- installation recommendations,
- recommended microbiol ogical decontamination procedure, and
- references and specifications pertinent to Class IIBiohazard Cabinetry.

While the NSF standard does not cover field testing of BSCs, it is common for many of its test methods and parameters to be applied in the field, and these are included in Annex "F" of the standard. Most recently revised in 1992 (with a new revision due in 2000),this Standard i

s reviewed periodically by a steering committee to ensure that it remains consistent with developing technologies. The operational integrity of a new BSC must be validated

before it is put into service or after a cabinet has been repaired or relocated. Relocating a BSC may break the HEPA filter seal s or otherwise damage the filters or the cabinet. Each BSC should be tested and certified at least annually to ensure continued proper operation.

Performance Testing BSCs in the Field

BSCs are the primary containment device that protect theworker, product and environm ent from exposure to microbiological agents. Their operation as specified by StandardNo. 49 needs to be verified at the time of installation and Certification of Biosafety Cabinets annually thereafter. The purpose and acceptance level of theperformance tests (Table 3) are to ensure the balance of inflowand exhaust air, the di stributi on of air onto the work surface, andthe integr ity of the cabinet. Other tests check electrical andphysical features of the BSC.

A. Downflow Velocity:

This test is performed to measure the velocity of air moving through the cabinet workspace, and is to be performed on all biosafety cabinets.

B. Inflow Velocity Test:

This test is performed to determine the calculated or directly measured velocity through the work access opening, to verify the nominal set point average inflow velocity and to calculate the exhaust airflow volume rate.

C. Airflow Smoke Patterns Tests:

This test is performed to determine if the airflow along the entire perimeter of the work access opening is inward, if airflow within the work area is d own ward with n o dead spots or refluxing, if ambient air passes onto or over the work surface, and if there is refluxing to the outside at the window wiper gasket and side seals. The smoke testis an indicator of airflow direction, not velocity.

D. HEPA Filter Leak Test:

This test is performed to determine the integrity of supply and exhaust HEPA filters, filter housing, and filter mounting frames while the cabinet is operated at the nominal set point velocities. An aerosol in the form of generated particulates of dioctylphthalate (DOP) or an accepted alternative (e.g., food grade corn oil, di(2-ethylhexyl), sebecate, polyethylene glycol, and medical grade light mineral oil) is required for leak -testing HEPA filters and their seals. Although DOP has been identified as a potential carcinogen, competent service personnel are trained to use this chemical in a safe manner. The aerosol is generated on the intake s ide of the

filter, and particles passing through the filter or around the seal are measured with a photomete r on the discharge side . This test is suitable for ascertaining the integrity of all HEPA filters.

E. Cabinet Leak Test:

The pressure holding test is performed to determine if exterior surfaces of all plenums, welds, Certification of Biosafety Cabinets gaskets , and plenum penetrations or seals are free of leaks. It need only be performed just prior to initial installation when the BSC is in a free - standing position (all four sides are easily accessible) in the room in which it will be used, after a cabinet has been relocated to a new location, and again after removal of access panels to plenums for repairs or a filter change. This test may also be performed on fully installed cabinets."Cabinet integrity can also be checked using the bubble test ".

F. Electrical Leakage and Ground Circuit Resistance and Polarity Tests :

These safety tests are performed to determine if a potential shock hazard exists by measuring the electrical leakage, polarity, ground fault interrupter function, and ground circuit resistance to the cabinet connection. They may beperfor med by an e lectrical technician other than the field certification personnel at the same time the other field certification tests are conducted. The polarity of electrical outlets are checked (see Table 3, E). The ground fault circuit interrupter should trip when approximately 5 milliamperes (ma) is applied.

G. Lighting Intensi ty Test:

This test is performed tomeasure the light intensity on the work surface of the cabinet as an aid in minimizing cabi net operator's fatigue.

H. Vibration Test:

This test is performed to determine the amount of vibration in an operating cabinet as aguide t o satisfactory mechanical performance, as an aid in minimizing cabinet operator's fatigue, and to prevent damage to delicate tissue culture specimens.

I. Noise Level Test:

This test is performed to measure the noise levels produced by the cabinets, as a guide to satisfactory mechanical performance and an aid in minimizing cabinet operator's fatigue.

J. UV Lamp Test :

A few BSC s have UV lam ps. Wh en use d, they must be test ed perio dically to ensu re that their energy output is sufficient to kill microo rganisms. Aft er having been t urned off and allow ed to c ool, the surfac e on the bulb should be cleaned with 70% ethanol prior to performing this test.

Certification of Biosafety Cabinets

Five minutes after the lamp has been turnedon, the sensor of theUV meter is placed in the cent er of the work surface. The radiation output should not be less than 40 micro watts per square centimeter at 254 nano meters (nm). Finally, accurate test results can only be assured when the testing equipment is properly maintained and calibrated . It is appropriate to request the calibration information for the test equipment being used by the certifier.

Work-related musculoskeletal disorders (WRMSDs): are described as wide range of degenerative and inflammatory conditions that affect the supporting blood vessels, peripheral nerves, joints, ligaments, tendons, and muscles. Such conditions could result in functional impairment and pain which are widely experienced at the upper extremities and the neck.

According to the National Institute for Occupational Safety and Health , musculoskeletal disorder (MSD) is a damage that affects the musculoskeletal system of the human body, especially at bones, spinal discs, tendons, joints, ligaments, cartilage, nerves, and blood vessels. Such injuries may result due to repetitive motions, forces, and vibrations on human bodies during executing certain job activities. Previous injuries, physical condition, heredity, pregnancy, lifestyle, and poor diet are the factors that contribute to the musculoskeletal symptoms.



Physical factors

These include intense, repeated, or sustained exertions; awkward, non-neutral, and extreme postures; rapid work pace; repeated and/or prolonged activity; insufficient time for recovery, vibration, and cold temperatures.

Inappropriate postures: The muscles and joints involved in an activity and the amount of stress or force tolerated or generated are determined by the body posture due to the fact that as the back bends, there is more stress exerted on the spinal discs during object lifting, handling, or lowering than when the back is straight. The tasks requiring sustained or repeated twisting or bending of the shoulders, wrists, hips, and the knees also increase the stress on the joints. Therefore, prolonged or frequent work activities can be very stressful.

Repetitive motions:Frequently repeated motions (e.g., every few seconds) and prolonged periods could end up in accumulated muscle-tendon strain and fatigue. If the time allocated between the exertions is sufficient, the muscles and tendons can recover from forceful exertions and stretching effects. During inappropriate postures and forceful exertions, the impact of repetitive motions due to performing the same work activities can be increased. Risk factor such as repetitive actions can also depend of the performed specific act and the body area.

Duration: The amount of time that someone is continuously exposed to a risk factor is called duration. The job tasks that require the use of the same motions or muscles for long periods increase the probability of general and local fatigue.

Frequency: Within a given period of time, the number of repeated exertions by a person is defined as frequency. In fact, if the exertion is repeated more often, the speed of movement of the exerted body part increases. Moreover, the recovery period decreases when more frequent exertion is completed, and this increases the probability of general and local fatigue with the duration.

Psychosocial factors:

WRMSDs do not only result in the physical stressors. However, a set of multiple factors determine the formation. Psychosocial risk factors such as stressful job, social pressure at work, and job dissatisfaction are such factors which contribute to the formation of WRMSDs. When an injury occurs, psychosocial factors, such as incongruous pain and depression, are the main reasons for the development of a disability and transition from acute to chronic pain .These include monotonous work, time pressure, a high workload, unorganized work-rest schedules, complexity of tasks, career concerns, lack of peer support, a poor relationship between workersand their supervisors, and poor organizational characteristics (climate, culture, and communications).

The way to structure and manage the work processes are called as organization of work and it deals with the following subjects:

- Work scheduling (work-rest schedules, work hours, and shift work).
- Job design (task complexity, required effort and skill, and the degree of control of work).
- Interpersonal facets of work (relationships with colleagues, subordinates, and supervisors).

- Concerns regarding career (job security and opportunities to grow).
- Style of management (teamwork and participatory management).
- Characteristics of the organization (culture, communication, and climate).

Many of the above components are called as "psychosocial factors," and they are known as risk factors for psychological strain and job stress. Stress is a conceived emotional and physical reaction of the human body to events or circumstances which cause excitement, danger, confusion, irritation, or frightening. Particularly, it is a transition from someone's normal behavior according to a cause that results in tear and wear on the body's mental or physical resources.

There are internal or external stimuli that cause stress. The internal stimuli are those stressors that involve self-expectations, impersonal barriers, and conflicting desires. Apparently, internal stimuli depend on personal aspects. However, external stimuli include situations where expectations, time limit, lack of resources, and lack of vision and goals present.

Stressors may be physiological, psychological, social, environmental, developmental, spiritual, or cultural and represent unmet needs. Stress causes changes in the human body that are usually centered on the nervous system and endocrine system. Therefore, the human body's internal environment is constantly changing, and the body's adaptive mechanisms continually function to adjustments in heart rate, respiratory rate, blood pressure, temperature, fluid and electrolyte balances, hormone secretions, and level of consciousness.Intensive and extensive stress results in disorders in the musculoskeletal system. Emotions like anger, frustration, irritation, confusion, tension, and nervousness cause the stress. It is not only the experience and frequency of such feelings but also the repetition of the activities and motions that induce injuries or musculoskeletal disorders.

In considering human emotions and feelings and applying the results of the research to their impact on the musculoskeletal system, it is probably platitudinous to make a statement that the greater the knowledge and understanding of the human being, the better the result obtained. In order to identify and understand the effect of the emotions on the musculoskeletal system, important risk factors for musculoskeletal disorders should be recognized.

Psychological risk factors

Moreover, together with the above conditions, some other work aspects contribute to both physical and psychological stress as well. The human body in fact is limited in kinematic motions as it is a mechanism formed by biological characteristics. Beyond this, it also includes a brain which thinks, reasons, and feels. Thus, feelings such as joy, pain, anger, sadness, depression, frustration, outrage, boredom, fear, jealousy, hate, love, and (even) schizophrenia are experienced by human beings. When exposed to stress, human beings show responses such as fear, frustration, anger, fatigue, tension, depression, anxiety, helplessness, confusion, and lack of vigor.

Common types of occupational MSDs

i. Tendonitis: it is the most common hand problem, which happens when the tendons connecting the fingers to muscles in the forearms get inflamed. Tendons help attach muscle to bone to allow movement of a joint

ii. Tenosynovitis: this is another common ailment, where the synovial sheaths (sacks filled with fluid) swell which surround and protect the tendons. Carpal tunnel syndrome (CTS) is the condition which is a result of this swelling. The carpal tunnel is a small opening close to the bottom of the hand which accommodates the tendons and the median nerve that provides sensation to the hand. In the case of swelling of the synovial sheaths, the carpal tunnel cramps and puts pressure on the nerve. There are several syndromes of the CTS, but the most frequent ones are numbness, tingling, or a burning sensation in the palms, fingers, and wrists. These conditions can lead to strength and sensation loss in the hands in time.

iii. Nerve compression: throughout the body, there are several nerves that transmit signals from the body parts to the brain. These often move in the spine through small tunnels available between the vertebrae. There are many conditions which cause the nerves to become compressed, pinched, or queezed, which can result in weakness, numbness, severe pain, and loss of coordination. The condition in which the sciatic nerve in the spine becomes compressed is known as sciatica. The symptoms of this condition appear in the back of the legand at the side of the foot .

iv. Raynaud's syndrome/disease: this is a loss of blood circulation, which results in whitening and numbness of the finders. It is sometimes called "white finger," "wax finger," or "dead finger".

v. Reflex sympathetic dystrophy: this is a rare, incurable condition characterized by fry, swollen hands and loss of muscle control. It is consistently painful.

vi. Ganglion cyst: this disorder arise when a swelling or lump in the wrist resulting from jellylike substance leaks from a joint or tendon sheath.

vii. Cervical radiculopathy: this is the condition of an injury due to the extending out of those nerves that provide sensation and trigger movement from cervical vertebrae which result in weakness, numbress, or pain in the hand, wrist, arm, or shoulder.

viii. Lateral epicondylitis: this is a condition when the outer part of the elbow becomes painful and tender, usually as a result of a specific strain, overuse, or a direct bang .

ix. Rheumatoid arthritis: this is a disabling autoimmune disease which is progressive and happens in a long term. It causes pain, swelling, and inflammation in and around the joints and other body organs. Hands and feet are affected mainly, but it can be seen in any joint as well. It usually occurs at the same joints on both sides of the body



SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – IV– Industrial safety – SBT1609

PERSONAL PROTECTIVE EQUIPMENTS

Personal protective equipments commonly referred to as "PPE "includes all clothing and work accessories designed to protect employees from injury or infection. It refers to the protective clothing, helmets, hard hats, hearing protectors, respirators, goggles or other garments or equipments meant to protect the wearers' body from injury by heat, chemicals, infection, electrical hazards, airborne

particulate matter etc. The purpose of personal protective equipment is to reduce employee exposure to hazards when engineering and administrative controls are not effective to reduce these risks.PPE does not eliminate the hazard but reduce the employees risk of exposure to accident causing situations.PPE protects only the

user and does not eliminate the hazard from the workplace.PPE is a second line of defense for employee protection. The first line of defense is to eliminate accident causing situations in the workplace.

CLASSIFICATION

Personal protective equipments can be broadly classified into

- 1. Non respiratory protective equipments
- 2. Respiratory protective equipments

Non- respiratory protective devices include Head protectors, eye protectors, handand arm protectors, foot and leg protectors, body protectors and skin protectors. Respiratory protective equipments include different kinds of breathing apparatus like filter respirators, airline respirators, self- contained breathing apparatus etc

When selecting a PPE to reduce a risk to health and safety, the employer should ensure that the PPE is

- Suitable for the nature of work and any hazard associated,
- A suitable size and fit and reasonably comfortable for the person to wear
- Maintained, repaired or replaced
- Used or worn by the worker ,so far as is reasonably practicable

Duties of employees on using PPE

• PPE must be worn and used in accordance with the instructions provided to them

- PPE must be examined before use
- Any defected must be immediately reported to the supervisor
- Employees must take care of the PPE provided to them

HEAD PROTECTION

An Injury to the head can pose serious threat to the brain. Therefore head protection is considered important. Head injuries are usually caused by the falling objects, bumping against a fixed object, contacting exposed electrical conductors etc.

Safety Helmets

A safety helmet must be worn where a person may be struck on the head by a falling body, flying objects, overhead spills of hot and corrosive chemicals, electric shock etc. A wide range of accessories can be fitted with the helmets for variable working conditions. The hard shell of the safety helmet is designed to protect the head against impact. Helmets are made out of materials such as fibre-glass reinforced plastic, HDPE, aluminium alloy etc.

To provide best protection, a safety helmet must fit properly. Care and Maintenance of helmets are essential. Helmets must be checked regularly for cracks or other damages. Helmets must be cleaned at least once in a month in warm water or recommended cleanser and air dried. The helmet must be protected from direct exposure to extreme conditions of heat and cold, chemicals etc.

Hard Hats

Safety hats protect the head from impact, penetration and electrical shock. A hard hat is a type of helmet predominantly used in workplace environments such as construction sites, to protect the head from injury. Hard hats are classified into three categories

Class A- General Service, limited voltage protection Class B - Utility Service, high voltage protection Class C - Special Service, no voltage protection

EAR PROTECTION

High noise levels is predominant in most industrial settings, carry a very serious impact on the employees. Hearing loss has an impact on the person's quality of life. Hearing loss can also affect the safety of the working environment when a worker can't hear a warning or alarm signal. People working in highly noisy areas must wear ear protection aids.

Ear Plugs

An ear plug is a device that is meant to be inserted in the ear canal to protect the wearer from loud noise, intrusion of water, foreign bodies, dust or excessive wind. Most earplugs are made of foam that is inserted into the ear canal. Ear plugs are rated with Noise Reduction Ratings which provide a guide to the noise protection provided by the device. Ear plugs may be better in hot, humid or confined work areas and better for employees who wear other personal protective equipments. The ear plugs may be disposable or reusable in nature. Disposable ear plugs are meant for one time usage and made of formable material. Reusable ear plugs are premolded and made of silicone, plastic or rubber.

Ear Muffs

Ear muffs are the objects designed to cover a person's ear for protection or for warmth. Ear muffs have cups and cushions that fit securely around the ears, covering them completely, and are held in place by a head band. Thermal ear muffs work in cold environment to keep a person's ear warm. Acoustic ear muffs protect the wearer from extreme noises.

EYE AND FACE PROTECTION

Eyes are vulnerable to mechanical, chemical and thermal hazards. The employer shall ensure that each affected employee uses appropriate eye or face protection when exposed to eye or face hazards from flying particles, molten metal, liquid chemicals, acids or caustic liquids, chemical gases or vapors, or potentially injurious light radiation.

OSHA suggests that eye protection be routinely considered for use by carpenters, electricians, machinists, mechanics, millwrights, plumbers and pipefitters, sheetmetal workers and tinsmiths, assemblers, sanders, grinding machine operators, sawyers, welders, laborers, chemical process operators and handlers, and timber cutting and logging workers. Employers of workers in other job categories should decide whether there is a need for eye and face PPE through a hazard assessment.

Examples of potential eye or face injuries include:

- **1.** Dust, dirt, metal or wood chips entering the eye from activities such as chipping, grinding, sawing, hammering, the use of power tools or even strong wind forces.
- **2.** Chemical splashes from corrosive substances, hot liquids, solvents or other hazardous solutions.
- **3.** Objects swinging into the eye or face, such as tree limbs, chains, tools or ropes.
- 4. Radiant energy from welding, harmful rays from the use of lasers or other radiant light (as well as heat, glare, sparks, splash and flying particles).Eye protection choices include the following

Safety Glasses

Safety glasses are the most commonly used form of eye protection. They are basically designed to provide protection from flying particles that may strike the eyes from the front. Ordinary prescription glasses do not provide adequate protection. It must confirm to the standards. All safety glasses should have side shields.

Goggles

Goggles are intended for use when protection is needed against chemicals or particles. Impact protection goggles which contain perforations on the sides of goggle are not to be used for chemical splash protection, therefore are not recommended.

Splash goggles which contain shielded vents at the top of the goggle are appropriate for chemical splash protection, and also provide limited eye impact protection. Goggles only protect the eyes, offering no protection for the face and neck.

Face Shields

Full face shields provide the face and throat and partial protection from flying particles and liquid splash. For maximum protection against chemical splash, a full face shield should be used in combination with chemical splash goggles. Face shields are appropriate as secondary protection when implosion (e.g. vacuum applications) or explosion hazards are present. Face shields which are contoured to protect the sides of the neck as well as frontal protection are preferred.

ARM AND HAND PROTECTION

Arms and hands are vulnerable to cuts, burns, bruises, electrical shock, chemical spills, and amputation.

Gloves

Gloves provide protection for the hands and arms from chemicals, temperature extremes, and abrasion.

Their proper selection is vital to their ability to protect. This is especially true when dealing with potential exposure to chemicals. It is imperative to remember that both the thickness and the type of material the glove is manufactured from affect the ability to serve as a barrier against a chemical.

Another factor in the selection of gloves is the wearer's need for dexterity. It is often advisable to reduce the size and thickness of the glove to increase the dexterity. Caution is also required when using gloves around moving equipment. Gloves should not be used by anyone whose hands are exposed to moving parts in which their hands could get caught.

The following is a general list of the types of gloves

- Disposable latex gloves
- Chemical resistant gloves
- Leather gloves
- Non asbestos heat-resistant gloves
- I metal-mesh gloves for operations cutters
- Cotton gloves.

FOOTPROTECTION

The toes, ankles and feet are exposed to a wide range of on the job injuries.Safety shoes and boots provide impact and compression protection for workers who handle heavy materials or work in areas where materials could roll or fall onto their feet. Foot protection is usually in the form of

steel-toed work boots, with a steel shank to protect the bottom of the foot from puncture wounds. In wet environments, steel-toed boots that are waterproof and slip-resistant may

be necessary. The hazards that workers are exposed to will determine what type of foot protection is most appropriate for the job.

RESPIRATORYPROTECTION

Respiratory hazards include airborne contaminants such as dusts, mists, fumes and gases or oxygen deficient atmospheres. A respirator is a protective face piece, hood or helmet that is designed to protect the wearer against various harmful airborne agents.

Respirators should not be

the first choice for respiratory protection in workplaces. They should only be used

- when following the "hierarchy of control" is not possible (elimination, substitution, engineering or administrative controls)
- while engineering controls are being installed or repaired
- when emergencies or other temporary situations arise (e.g., maintenance operations) The two main types are air-purifying respirators (APRs) and supplied-air respirators (SARs).

Air-purifying respirators can remove contaminants in the air that you breathe byfiltering out particulates (e.g., dusts, metal fumes, mists, etc.). Other APRs purify air by adsorbing gases or vapours on a sorbent (adsorbing material) in a cartridge or cannister. They are tight-fitting and are available in several forms

- mouth bit respirator (fits in the mouth and comes with a nose clip to hold nostrils closed -
- for escape purposes only)
- quarter-mask (covering the nose and mouth),
- half-face mask (covering the face from the nose to below the chin), or
- full facepiece (covering the face from above the eyes to below the chin).

Respirators with a full face piece also protect the eyes from exposure to irritating chemicals.

Supplied-air respirators (SARs) supply clean air from a compressed air tank or through an air line. This air is not from the work room area. The air supplied in tanks or from compressors must meet certain standards for purity and moisture content

Supplied-air respirators may have either tight-fitting or loose-fitting respiratory inlets.

Respirators with tight-fitting respiratory inlets have half or full facepieces. Types with loose-

fitting respiratory inlets can be hoods or helmets that cover the head and neck, or loosefitting

facepieces with rubber or fabric side shields. These are supplied with air through airlines.

Examples of these classes of respirators include:

Air-purifying respirators (APRs)

- particulate respirators (previously called dust, fume, and mist respirators or masks),
- chemical cartridge respirators that can have a combination of chemical cartridges, along with a dust prefilter: this combination provides protection against different kinds of
- contaminants in the air
- gas masks (contain more adsorbent than cartridge-type respirators and can provide a higher level of protection than chemical cartridge respirators)
- powered air-purifying respirators (PAPRs). Supplied-air respirators (SARs)
- self-contained breathing apparatus (SCBA),
- airline supplied-air respirators,
- protective suits that totally encapsulate the wearer's body and incorporate a life- support system.

There are some combinations of airline respirators and SCBAs that allow workers to work for extended periods in oxygen-deficient areas or where there are airborne toxic contaminants. The auxiliary or backup SCBA source allows the worker to escape with an emergency source of air if the airline source fails.

There are also combination air-purifying and atmosphere supplying respirators.

These will offer worker protection if the supplied-air system fails, if the appropriate airpurifier units are selected.

These cannot be used in oxygen-deficient areas or where the air concentration of a contaminant exceeds the IDLH level (i.e., immediately dangerous to life or health).

Since filters capture particles, caution must be exercised to always check that these filters are not clogged as it makes it harder for air to pass through and increase the likelihood of contaminated air entering the mask. Cartridges can also become "full" or saturated. It will

stop working and "breakthrough" will occur - this term means that the gases or vapours will leak through the cartridge. Both cartridges and filters must be replaced on a regular basis by using the manufacturer's recommendations (usually determined by using warning properties or end-of- service indicators).

There are 9 classes of particulate filters, depending on the particulate material. They are also classified based on levels of oil resistance and filter efficiency. Oil can break down certain types of filters which means it is important to know the materials you are working with at all times and always select the right cartridge for your respirator.

The main categories are:

- N series (Not resistant to oil) May be used in any atmosphere where there is no oil particulate.
- R series (Resistant to oil) May be used in any atmosphere where there is no oil particulate, or up to one shift where there is oil particulate present. "One shift" means eight hours of continuous or intermittent use.

P series (Oil-Proof) - May be used in any atmosphere, including those with oil particulates, for more than one shift. If the filter is used in atmospheres with oil particulates, contact the manufacturer to find out the service life of the filter.

Work Stress:

Poor work organization, that is the way we design jobs and work systems, and the way we manage them, cause work stress.Excessive and unmanageable demands and pressures can be caused by poor work design, poor management and unsatisfactory working conditions. Stress related Hazards

Job content:

Montonous, understimulating, meaningless tasks, lack of variety, unpleasant task and aversive tasks

Work load and Work pace: Having too much or too little to do and Working under time pressures.

Working Hours: Strick and inflexible working schedules, long and unsocial hours, unpredictable working hours and badly designed shift systems

Participation and control: Lack of participation in decision making and lack of control

Organisational culture: Poor communication, poor leadership and lack of clarity about organizational objectives and structure.

Home and work interface: conflicting demands of work and home, lack of support for domestic problems at work and lack of support for work problems at home.

EFFECTS OF WORK STRESS

- 1. Become increasingly distressed and irritable
- 2. Become unable to relax or concentrate
- 3. Have difficulty thingking logically and making decisions
- 4. Enjoy their work less and feel less committed to it
- 5. Feel tired, depressed, anxious
- 6. Have difficulty sleeping
- 7. Serious physical problems-heart disease, disorders of digestive system, increases in blood pressure and head ache

Prevention of work stress

There are number of ways by which the risk of work stress can be reduced. These include

Primary prevention, reducing stress through:

- Ergonomics
- Work and environmental design
- Organizational and management development

Secondary prevention

Worker education and training

Tertiary prevention

Developing more sensitive and responsive management systems and enhanced occupational health provision.



SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – V– Industrial safety – SBT1609

Guidelines and regulations

1. Research: The levels of the risk and the classification of the organisms within these levels based on pathogenicity and local prevalence of diseases and on epidemic causing strains in India are defined in the guidelines. Some of the microorganisms not native to the country have been assigned to a special category requiring highest degree of safety. These include Lassa virus, Yellow fever virus etc. Appropriate practices, equipment and facilities are recommended for necessary safeguards in handling organisms, plants and animals in various risk groups. The guidelines employ the concept of physical and biological containment and also based upon the principle of good laboratory practice (GLP). In this context, biosafety practices as recommended in the WHO laboratory safety Manual on genetic engineering techniques involving microorganisms of different risk groups have incorporated in the guidelines (Chapter IV).

2. Large scale operations: The concern does not diminish when it comes to the use of recombinant organisms scale fermentation operations on large scale fermentation operations or applications of it in the environment. As such, the guidelines prescribe criteria for good large scale practices (GLSP) for using recombinant organisms. These include measures such as proper engineering for containment, quality control, personnel protection, medical surveillance, etc.

3. Environmental risks: Application and release of engineered organisms into the environment could lead to ecological consequences and potential risks unless necessary safeguards are taken into account. The guidelines prescribe the criteria for assessment of the ecological aspects on a case by case basis for planned introduction of rDNA organism into the environment. It also suggests regulatory measures to ensure safety for import of genetically engineered materials, plants and animals. The recommendations also cover the various quality control methods needed to establish the safety, purity and efficacy of rDNA products.

II.GUIDELINES

1. Definition of recombinant DNA: Recombinant deoxyribonucleic acid (rDNA) by definition involves in vitro introduction of different segments of DNA (one being the vector and the others normally unrelated DNA sequences) that are capable of replication in a host cell either autonomously or as an integral part of host's genome and maintenance of their continued propagation. This will include all types of cell fusion, microinjection of DNA or RNA or parts or all of chromosomes, genetic engineering including self cloning and deletion as well as cell hybridation, transformation and other types of virus or pathogen introduction into unnatural hosts.

2. Classification of a pathogenic microorganisms

2.1 The classification of infective microorganisms are drawn up under 4 risk groups in increasing order of risk based on the following parameters:

•pathogenecity of the agent

•modes of transmission and host range of the agent

•availability of effective preventive treatments or curative medicines

•capability to cause diseases to humans/animals/plants

•epidemic causing strains in India

The above mentioned parameters may be influenced by levels of immunity, density and movement of host population, presence of vectors for transmission and standards of environmental hygiene.

An inventory of pathogenic organisms classified in different groups is provided in Chapter V: A1. The scientific considerations for assessment of potential risks in handling of pathogenic organisms include the following:

i)Characterisation of donor and recipient organisms

ii)Characterisation of the modified organism

iii)Expression and properties of the gene product

2.2 Based on the risk assessment information, the probability of risk could be further assigned certain quantitative values (Chapter V: A7) for categorisation of experiments in terms of the following:

i)access factor of the organism

ii) expression factor of DNA

iii)damage factor of the Biologically active substance

3. Containment

Containment facilities for different Risk Groups as per the recommendations of World Health Organization (WHO)

The term "Containment" is used in describing the safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained.

Purpose of containment

To reduce exposure of laboratory workers, other persons, and outside environment to potentially hazardous agents.

Types of containment

3.1 Biological containment (BC): In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which is to provide biological containment must be chosen or constructed to limit the infectivity of vector to specific hosts and control the host-vector survival in the environment. These have been categorized into two levels - one permitting standard biological containment and the other even higher that relates to normal and disabled host-vector systems respectively (Chapter V: A3).

3.2 Physical Containment (PC): The objective of physical containment is to confine recombinant organisms thereby preventing the exposure of the researcher and the environment to the harmful agents. Physical containment is achieved through the use of i) Laboratory Practice, ii) Containment Equipment, and iii) Special Laboratory Design. The protection of personnel and the immediate laboratory environment from exposure to infectious agents, is provided by good microbiological techniques and the use of appropriate safety equipment, (Primary Containment).

The protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices, (Secondary Containment).

3.3 Elements of Containment: The three elements of containment include laboratory practice and technique, safety equipment and facility design.

i)Laboratory practice and technique:

- •Strict adherence to standard microbiological practices and techniques
- •Awareness of potential hazards
- •Providing/arranging for appropriate training of personnel
- •Selection of safety practices in addition to standard laboratory practices if required

•Developing of adopting a biosafety or operations manual which identifies the hazards

ii) Safety equipment (primary barriers): Safety equipment includes biological safety cabinets and a variety of enclosed containers (e.g. safety centrifuge cup). The biological safety cabinet (BSC) is the principal device used to provide containment of infectious aerosols generated by many microbiological procedures. Three types of BSCs (Class I, II, III) are used in microbiological laboratories. Safety equipment also includes items for personal protection such as gloves, coats, gowns, shoe covers, boots, respirators, face shields and safety glasses, etc.

iii) Facility Design (Secondary barriers): The design of the facility is important in providing a barrier to protect persons working in the facility but outside of the laboratory and those in the community from infectious agents which may be accidentally released from the laboratory. There are three types of facility designs: viz, the Basic Laboratory (for Risk Group I and II), the Containment Laboratory (for Risk Group III) and the Maximum Containment Laboratory (for Risk Group IV).

4. Bio-safety levels: It consists of a combination of laboratory practices and techniques, safety equipment and laboratory facilities appropriate for the operations performed and the hazard posed by the infectious agents. The guidelines for Microbiological and Biomedical Laboratories suggest four Biosafety levels in incremental order depending on the nature of work. Additional flexibility in containment levels can be obtained by combination of the physical with the biological barriers. The proposed safety levels for work with recombinant DNA technique take into consideration the source of the donor DNA and its disease-producing potential. These four levels corresponds to (P1<P2<P3<P4) facilities approximate to 4 risk groups assigned for etiologic agents.

These levels and the appropriate conditions are enumerated as follows:

4.1 Biosafety Level 1: These practices, safety equipment and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories and for other facilities in which work is done with defined and characterised strains of viable microorganisms not known to cause disease in healthy adult human. No special accommodation or equipment is required but the laboratory personnel are required to have specific training and to be supervised by a scientist with general training in microbiology or a related science.

4.2 Biosafety Level 2: These practices, safety equipment and facilities are applicable in clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Laboratory workers are required to have specific training in handling pathogenic agents and to be supervised by competent scientists. Accommodation and facilities including safety cabinets are prescribed, especially for handling large volume are high concentrations of agents when aerosols are likely to be created. Access to the laboratory is controlled.
4.3 Biosafety level 3: These practices, safety equipment and facilities are applicable to clinical, diagnostic, teaching research or production facilities in which work is done with indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Personnel are required to have specific training in work with these agents and to be supervised by scientists experienced in this kind of microbiology. Specially designed laboratories and precautions including the use of safety cabinets are prescribed and the access is strictly controlled.

4.4Biosafety level 4: These practices, safety equipment and facilities are applicable to work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Strict training and supervision are required and the work is done in specially designed laboratories under stringent safety conditions, including the use of safety cabinets and positive pressure personnel suits . Access is strictly limited.

A specially designed suit area may be provided in the facility. Personnel who enter this area wear a one-piece positive pressure suit that is ventilated by a life support system. The life support system is provided with alarms and emergency break-up breathing air tanks. Entry to this area is through an airlock fitted with air tight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air form the suit area is filtered by two sets of HEPA filters installed in the series. A duplicate filtration unit, exhaust fan and an automatically starting emergency power source are provide. The air pressure within the suit area is lower than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the inner shell of the suit area are sealed. A double door autoclave is provided for decontamination of disposable waste materials from the suit area.

5.Guidelines for rDNA research activities: The guidelines stipulate three categories of research activities, These are:

5.1Category I: Which are exempt for the purpose of intimation and approval of competent authority.

(i)The experiments involving self cloning, using strains and also inter-species cloning belonging to organism in the same exchanger group (Vide Chapter-V A4, A5).

(ii)Organelle DNA including those from chloroplasts and mitochondria.

(iii)Host-vector systems consisting of cells in culture and vectors, either non-viral or viral containing defective viral genomes (except from cells known to harbour class III, IV and special category etiologic agents listed under Chapter V: A1.

5.2Category II: Those requiring prior intimation of competent authority.

(i)Experiments falling under containment levels II, III and IV.

(ii)Experiment wherein DNA or RNA molecules derived from any source except for eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organisms and propagated under conditions of physical containment PC1 and appropriate to organism under study.

(iii)Experiments involving non pathogen DNA vector systems and regeneration from single cells.

(iv)Large scale use of recombinants made by self cloning in systems belonging to exempt category (e.g. E.coli, Saccharomyces, and B. subtilis)

5.3Category III: Those requiring review and approval of competent authority before commencement.

(i)Toxin gene clonings : A list of toxins classified based on their potential toxicity is listed in Chapter V - A6. The number of plasmid toxin gene clonings at present going on are only three viz. B. subtilis and B. sphericus toxin genes are cloned in B. subtilis and cholera toxin genes and B. thuringiensis crystal protein genes cloned in E.coli K12. These toxins gene cloning are being done under PC1 and BC 1 Containment conditions. All toxin gene cloning experiments producing LD50 less than 50 ug/kg of body weight of vertebrates (Chapter V-A6) or large scale growing may be referred to Institutional Biosafety Committee (IBSC) for clearance.

(ii)Cloning of genes for vaccine production: e.g. Rinderpest and leprosy antigens. Rinderpest has been classified under Risk Group II in view of the common incidence of the disease in India, though it is listed under special category in the Centres for Disease Control & National Institute of Health (CDC-NIH) system. Similarly, leprosy afflicts a large segment of population which calls for concerted programme to control the disease by vaccination and detection at early stages through immunodiagnostic tests. The containment should be decided by Review Committee on Genetic Manipulation (RCGM) on a case by case basis on experiment utilising DNA from non-defective genomes of organisms recognised as pathogen. In view of no demonstrated risk from handling free M. laprae antigens, inactivated whole cells as well as antigens can be assigned to Risk Group I. The details of the rDNA technology in development of vaccines for human and animal health giving containment conditions for observance of safeguards in large scale operations are given in Chapter V-B.

(iii)Cloning of mosquito and tick DNA experiments should be prescribed on a case by case basis since these are natural vectors for certain endemic viral and parasitic diseases.

(iv)Genes coding for antibiotic resistance into pathogenic organisms which do not naturally possess such resistance.

(v)Introduction into cultured human cells of recombinant DNA molecules containing complete genes of potentially oncogenic viruses or transformed cellular genes.

(vi)Introduction into animal cells of unidentified DNA molecules derived from cancer cells or in vitro transformed cells.

(vii)Experiments involving the use of infectious animal and plant viruses in tissue culture systems.

(viii)Experiments involving gene transfer to whole plants and animals.

(ix)Cell fusion experiments of Animal cells containing sequences from viral vectors if the sequence lead to transmissible infection either directly or indirectly as a result of complementation or recombination in the animals. For experiments involving recombinant DNA of higher class organisms using whole animals will be approved on case by case following IBSC review.

(x)Transgenosis in animal experiments : Transgenosis method is used to transform animal cells with foreign DNA by using viruses as vectors or by microinjection of DNA into eggs and preembryos. The expression of an inserted gene can be influenced both by the regulatory sequences associated with the gene and the sequences present at the site of integration of host genome. At present, there is no way to control where a gene is inserted into the chromosome of either an animal or plant cell. Yet this site of insertion can affect not only the expression of the interested gene but also the regulation of the host cells- DNA e.g. by non-specific activation of cellular protooncogenes.

(xi)All experiments involving the genetic manipulation of plant pathogens and the use of such genetically manipulated plant pathogens would require approval of competent authority (IBSC).

(xii)Transfer of genes with known toxicity to plants using Agrobacterium tumefaciens or other vectors. Attempts are under way using Ti-plasmid, A. tumefaciens and other vectors to transfer toxin-encoding genes that enable plants to make their own insecticide, resist infections or tolerate a variety of environmental stresses. Case by case clearance is needed though exemption may be made for the use of well characterized vectors and non-toxic genes.

(xiii)In case of plant viruses, permission may be obtained only when it is known that there is a chance of non-species specific spread of infection to plants that could produce changes in pathogenicity, host range or vector transmissibility. The growth of whole plants, propagation of genetically manipulated organisms in plants, regeneration of plants from cells transformed by manipulated plant pathogen vector would require containment conditions that are elaborated in Chapter V: C2.

(xiv)Experiments requiring field testing and release of rDNA engineered microorganisms and plants (Chapter V: C3).

(xv)Experiments involving engineered microbes with deletions and certain rearrangements.

(xvi)Diagnostics: No major risk can be foreseen on diagnostics involving in vitro tests. But for diagnostics involving in vivo tests, specific containment levels have to be prescribed on case by case basis. For example, tuberculin moiety could be cloned and used for in vivo hypersensitivity test as a diagnostic method.

(xvii)Gene therapy for hereditary diseases of genetic disorders.

6.Large scale experiments: Large scale production of bio-molecules from genetically engineered microorganisms have not just been taken up in the country. However, the use of recombinant organisms in large scale operations is expected in the near future.

6.1In the guidelines, experiments beyond 20 litres capacity for research as well as industrial purposes are included in the category of large scale experimentation/operations.

6.2For such activities it is recommended that one should seek approval of the competent authority as described in Chapter-III. In order to seek approval it will be necessary to furnish the relevant details in a prescribed format on the lines suggested by GEAC.

6.3For good large scale practice (GLSP) as well as levels of containment, the following principles of occupational safety and hygiene will be applied.

i)to keep work place and environment exposure to any physical, chemical or biological agent to the lowest practicable level;

ii)to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary ;

iii)to test adequately and maintain control measures and equipment ;

iv)to test when necessary for the presence of viable process organisms outside the primary physical containment ;

v)to provide training of personnel

vi)to formulate and implement local code of practice for the safety of personnel.

6.4The following safety criteria are to be compiled with for good large scale practice:

i)The host organism should not be a pathogen, should not contain adventitious agents, and should have an extended history of safe use, or have built-in environmental limitations that permit optimum growth in the bioreactor but limited survival with no adverse consequences in the environment.

ii)The vector/insert should be well characterised and free from known harmful sequences; the DNA should be limited in size as much as possible to perform the intended function; should not increase the stability of the recombinant in the environment unless that is a requirement of the

intended function; should be poorly mobilisable; and should not transfer any resistance markers to microorganisms not known to acquire them naturally if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture.

iii) The genetically manipulated organism should not be a pathogen and should be assessed as being as safe in the bio-reactor as the host organism, and without adverse consequences in the environment

6.5 The physical containment conditions that should be ensured for large scale experiments and production activities are given in Chapter V: B1.

7. Release to the environment:

7.1 Depending on the types of organisms handled and assessment of potential risks involved appropriate containment facilities must be provided to ensure safety of worker and to prevent unwanted release in the environment.

7.2 Biowastes resulting from laboratory experiments, in industrial operations should be properly treated so that the pathogenicity of genetically engineered organisms are either destroyed or rendered harmless before disposal in the environment. Special facilities should be created for disposal of experimental animals. All refuse and carcasses must be incinerated. Exemption/relaxation of safety measures on specific cases may be considered based on the risk assessment criteria.

7.3 For planned release of organisms into the environment, the following points should be taken into consideration:

i)Geographical location, size and nature of the site of release and physical and biological proximity to man and other significant biota. In case of plants, proximity to plants which might be cross pollinated.

ii)Details of target ecosystem and the predicted effects of release on that ecosystem.

iii)Method and amount of release, rate frequency and duration of application.

iv)Monitoring capabilities and intentions: how many novel organisms be traced, e.g. to measure effectiveness of application.

v)Onsite worker safety procedures and facilities.

vi)Contingency plans in event of unanticipated effects of novel organisms.

It is important to evaluate rDNA modified organism for potential risk prior to application in agriculture and environment. Prior to introduction of micro-organisms, properties of the

organism, the possible interaction with other disease causing agents and the infected wild plant species should be evaluated. An independent review of potential risks should be conducted on a case by case basis prior to application. Details of points to be taken into account for risk assessment of genetically altered organisms while making proposals for release applications are given at Chapter V:D1. The bio-hazard evaluation of viral, bacterial, insecticidal agents for field applications are provided in Chapter V:C4. Development of organisms for agricultural or environmental applications should be conducted in a stepwise fashion, moving where appropriate, from the laboratory to the growth chamber and green house under containment conditions and good laboratory practice. It should be done under expert advice of competent authority with regard to the area to be covered taking into account the experimental design and condition of isolation. Release of any strain for field testing should be done with the permission of Genetic Engineering Approval Committee (GEAC) as mentioned at Chapter III.

Though, manipulation of plants under containment would not require regulatory clearance of GEAC, testing of altered plant material in the environment however should follow regulatory guidelines seeking experimental field use permit from GEAC even though prima facie, plant material appears safe to test under containment conditions. License for large scale release in case of genetically engineered plants tested pathogens is required.

8. Import and shipment:

8.1 The import or receipt of etiologic agents and vectors of human and animal disease or their carriers is subject to the quarantine regulations. Permits authorising the import or receipt of regulated materials for research (e.g. toxin genes, hybridomas, cell cultures, organelle) and specifying conditions under which the agent or vector is shipped, handled and used are issued by the Review Committee on Genetic Manipulation while large scale imports for industrial use are regulated by Genetic Engineering Approval Committee and are mentioned in Chapter III. Safety testing may be required to ensure that it is far from risk.

8.2 The Inter-State shipment of indigenous etiologic agents, diagnostic specimens and biologicals products is subject to applicable packaging, labeling and shipping requirements specified for etiologic agents. Packaging and labeling requirements for Inter-state shipment of etiologic agents are summarised and illustrated in the rDNA booklet. All such shipments would need the clearance of Institutional Biosafety Committee mentioned in Chapter III.

9. Quality control of biologicals produced by rDNA technology: The general regulations normally applicable for biologicals are applicable to the recombinant DNA products. The specific relevant aspects to a particular product should be discussed with the appropriate Government Agency on a case by case basis.

9.1 A new license for the product or drug application would be required on products made of recombinant DNA technology even if the product is considered to be chemically and physically

similar to the naturally occurring substance or previously approved product produced in conventional system

MECHANISM OF IMPLEMENTATION OF BIOSAFETY GUIDELINES

For implementation of the guidelines it is necessary to have an institutional mechanism to ensure the compliance of requisite safeguards at various levels. The guidelines prescribe specific actions that include establishing safety procedures for rDNA research, production and release to the environment and setting up containment conditions for certain experiments. The guidelines suggest compliance of the safeguards through voluntary as well as regulatory approach. In this connection, it is proposed to have a mechanism of advisory and regulatory bodies to deal with the specific and discretionary actions on the following:

a.Self regulation and control in the form of guidelines on recombinant research activities; and

b.Regulation of large scale use of engineered organisms in production activity and release of organisms in environmental applications under statutory provisions.

The institutional mechanism as proposed for implementation of guidelines is shown in organogram in Figure 2. Mainly it consists of the following:-

i)Recombinant DNA Advisory Committee (RDAC)

ii)Institutional Biosafety Committee (IBSC)

iii)Review Committee on Genetic Manipulation (RCGM)

iv)Genetic Engineering Approval Committee (GEAC)

Scope and functions of advisory committee and statutory body

1. Recombinant DNA Advisory Committee (RDAC): The Committee should take note of developments at national and international levels in Biotechnology towards the currentness of the safety regulation for India on recombinant research use and applications. It would meet once in 6 months or sooner for this purpose.

The specific terms of reference for Recombinant Advisory Committee include the following :

i)To evolve long term policy for research and development in Recombinant DNA research.

ii)To formulate the safety guidelines for Recombinant DNA Research to be followed in India.

iii)To recommended type of training programme for technicians and research fellows for making them adequately aware of hazards and risks involved in recombinant DNA research and methods of avoiding it. 2. Implementation Committees:

2.1 Institutional Biosafety Committee (IBSC)

Institutional Biosafety Committee (IBSC) are to be constituted in all centres engaged in genetic engineering research and production activities. The Committee will constitute the following:

(i)Head of the Institution or nominee

(ii)3 or more scientists engaged in DNA work or molecular biology with an outside expert in the relevant discipline.

(iii)A member with medical qualifications - Biosafety Officer (in case of work with pathogenic agents/large scale use).

(iv)One member nominated by DBT.

2.2 The Institutional Biosafety Committee shall be the nodal point for interaction within institution for implementation of the guidelines. Any research project which is likely to have biohazard potential (as envisaged by the guidelines) during the execution stage or which involve the production of either microorganisms or biologically active molecules that might cause biohazard should be notified to IBSC. IBSC will allow genetic engineering activity on classified organisms only at places where such work should be performed as per guidelines. Provision of suitable safe storage facility of donor, vectors, recipients and other materials involved in experimental work should be made and may be subjected to inspection on accountability.

The biosafety functions and activity include the following:

i)Registration of Bio-safety Committee membership composition with RCGM and submission of reports.

IBSC will provide half yearly report on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations if any. A computerised Central Registry for collation of periodic report on approved projects will be set up with RCGM to monitor compliance on safeguards as stipulated in the guidelines.

ii)Review and clearance of project proposals falling under restricted category that meets the requirements under the guidelines.

IBSC would make efforts to issue clearance quickly on receiving the research proposals from investigators.

iii)Tailoring biosafety programme to the level of risk assessment.

iv)Training of personnel on biosafety.

v)Instituting health monitoring programme for laboratory personnel.

complete medical check-up of personnel working in projects involving work with potentially dangerous microorganisms should be done prior to starting such projects. Follow up medical checkups including pathological tests should be done periodically, at least annually for scientific workers involved in such projects. Their medical records should be accessible to the RCGM. It will provide half yearly reports on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations if any.

vi)Adopting emergency plans.

3. Review Committee on Genetic Manipulation (RCGM): The RCGM will have the following composition:

i)Department of Biotechnology

ii)Indian Council of Medical Research

iii)Indian Council of Agricultural Research

iv)Council of Scientific & Industrial Research

v)Three Experts in Individual capacity

vi)Department of Science & Technology

The RCGM will have the functions:

i)To establish procedural guidance manual - procedure for regulatory process with respect to activity involving genetically engineered organisms in research, production and applications related to environmental safety.

ii)To review the reports in all approved ongoing research projects involving high risk category and controlled field experiments, to ensure that safeguards are maintained as per guidelines.

iii)To recommended the type of containment facility and the special containment conditions to be followed for experimental trials and for certain experiments.

iv)To advise customs authorities on import of biologically active material, genetically engineered substances or products and on excisable items to Central Revenue and Excise.

v)To assist Department of Industrial Development, Banks towards clearance of applications in setting up industries based on genetically engineered organisms.

vi)To assist the Bureau of Indian Standards to evolve standards for biologics produced by rDNA technology.

vii)To advise on intellectual property rights with respect to rDNA technology on patents.

3.1 The RCGM would have a Research Monitoring function by a group consisting of a smaller number of individuals (3 or 4). The monitoring group would be empowered to visit experimental facilities in any laboratory in India where experiments with biohazard potential are being pursued in order to determine the Good Laboratory practice and conditions of safety are observed.

3.2 In addition, if the RCGM has reasons to believe that there is either actual or potential danger involved in the work carried out by any laboratory (which might or might not have obtained prior clearance for the project), the monitoring group would be empowered to inspect the facility and assess the cause of any real or potential hazard to make appropriate recommendation to the RCGM. RCGM would be empowered to recommend alteration of the course of experiments based on hazard considerations or take steps to cancel the project grant, in case of deliberate negligence and to recommend appropriate actions under the provisions of Environmental Protection Act (EPA) where necessary.

4. Genetic Engineering Approval Committee (GEAC): Genetic Engineering Approval Committee (GEAC) will function under the Department of Environment (DOEn) as statutory body for review and approval of activities involving large scale use of genetically engineered organisms and their products in research and development, industrial production, environmental release and field applications.

The functions include giving approval from environmental angle on:

i)Import, export, transport, manufacture, process, selling of any microorganisms or genetically engineered substances or cells including food stuffs and additives that contains products derived by Gene Therapy.

ii)Discharge of Genetically engineered/classified organisms/cells from Laboratory, hospitals and related areas into environment.

iii)Large scale use of genetically engineered organisms/classified microorganisms in industrial production and applications. (Production shall not be commenced without approval).

iv)Deliberate release of genetically engineered organisms. The approval will be for a period of 4 years.

The composition of the Committee would be as follows:

1. Chairman - Additional Secretary, Department of Environment

Co-Chairman - Expert Nominee of Secretary, DBT.

2. Representatives of concerned Agencies and Departments:

- •Ministry of Industrial Development
- •Department of Science & Technology

•Department of Ocean Development

•Department of Biotechnology

3.Expert Members:

•Director-General, Indian Council of Agricultural Research

•Director General, Indian Council of Medical Research

•Director-General, Council of Scientific & Industrial Research

- •Director-General, Health Services (Ministry of Health & Family Welfare)
- •Plant Protection Adviser (Ministry of Agriculture)
- •Chairman, Central Pollution Control Board
- •3 Outside experts in individual capacity.
- 4.Member Secretary Official of, DOEn

4.1 GEAC will have the Biotechnology Coordination Committees under it which will functions as legal and statutory body with judicial powers to inspect, investigate and take punitive action in case of violations of statutory provisions under EPA.

i)Review and control of safety measures adopted while handling large scale use of genetically engineered organisms/classified organisms in research, developmental and industrial production activities.

ii)Monitoring of large scale release of engineered organisms/products into environment, oversee field applications and experimental field trials.

iii)To provide information/data inputs to RCGM upon surveillance of approved projects under industrial production, and in case of environmental releases with respect to safety, risks and accident.

4.2 Statutory rules and regulations to be operated by the GEAC would be laid down under the Environment Protection Act, 1986.

5. Funding Agency

5.1 The funding agency will be responsible for approval and clearing of research proposals for grants in aid in respect of rDNA research activities. The funding agency at the centre and state level will be advised to ensure that the guidelines are taken into account for compliance while supporting grants on research projects. Investigators will be required to submit as part of the project application an evaluation of biohazards that may arise and also the requirement on the type of containment facility, certified by IBSC. The funding agency should state clearly that support on approved projects will be withdrawn in case of deliberate violation or avoidable negligence of the rDNA guidelines. The investigators will also be asked to make a declaration in their publications that the work was carried out following the national guidelines. The funding agency will annually submit to RCGM the list of approved projects that come under high risk categories.

5.2 The concerned institutions will be instructed to the effect that initiation and execution of any research project, production activity and field trials should be preceded by necessary procedures of notification and approval of the competent authority including IBSC, GEAC depending on the nature of projects and activities.

6.Initially, to familiarize the R&D groups in industry and other institutions the guidelines will be widely publicised through scientific journals and popular science magazines. Workshops and group discussions will be organised in R&D institutes, and other places to fulfill the need for public information on safety aspects of rDNA technology. Steps will be taken to introduce courses in biohazards and safety procedures for personnel working in areas which are likely to involve biohazards as part of the training programme.

What is Risk Analysis?

After identifying and classifying the risks, we are going to proceed with their analysis, that is, the possibility and the consequences of each risk factor are examined in order to establish the level of riskof our project.

Risk Analysis Method

There are three kinds of methods used for determining the level of risk of our business. The methods can be: Qualitative Methods – Quantitative Methods – Semi-quantitative Methods.

Qualitative Methods:

This is the kind of risk analysis method most often used for decision making in business projects; entrepreneurs base themselves on their judgment, experience and intuition for decision making.

These methods can be used when the level of risk is low and does not warrant the time and resources necessary for making a full analysis.

These methods are also used when the numerical data available are not adequate for a more quantitative analysis that would serve as the basis for a subsequent and more detailed analysis of the entrepreneur's global risk.

The qualitative methods include:

- Brainstorming
- Questionnaire and structured interviews
- Evaluation for multidisciplinary groups
- Judgment of specialists and experts (Delphi Technique)

Semi-Quantitative Methods:

Word classifications are used, such as high, medium or low, or more detailed descriptions of likelihood and consequences.

These classifications are shown in relation on appropriate scale for calculating the level of risk. We need to give careful attention to the scale used in order to avoid misunderstandings or misinterpretations of the results of the calculation.

Quantitative Methods:

Quantitative methods are considered to be those that enable us to assign values of occurrence to the various risks identified, that is, to calculate the level of risk of the project.

- Los quantitative methods include:
- Analysis of likelihood
- Analysis of consequences
- Computer simulation

The development of these measurements can be effected by means of different mechanisms, among which we note particularly the Monte Carlo Method, which is characterized by:

- A broad vision in order to show a range of possible scenarios
- Simplicity in putting it into practice
- Suitable for performing computer simulations.
- Seeks to represent reality through a mathematical risk model.