



# Hazard Analysis & Risk Assessment

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# Introduction

A **hazard analysis** is a process used to assess risk. The results of a hazard analysis is the identification of unacceptable risks and the selection of means of controlling or eliminating them. The term is used in several engineering specialties, including avionics, chemical process safety, safety engineering and food safety. Alternative definitions include:

Identification, studies and monitoring of any hazard to determine its potential, origin, characteristics and behaviour.

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

An analysis or identification of the hazards which could occur at each step in the process, and a description and implementation of the measures to be taken for their control.

## ***Hazards and risk***

A hazard is defined in FAA Order 8040.4 as a "Condition, event, or circumstance that could lead to or contribute to an unplanned or undesirable event." Seldom does a single hazard cause an accident. More often, an accident occurs as the result of a sequence of causes. A hazard analysis will consider system state, for example operating environment, as well as failures or malfunctions.

While in some cases safety risk can be eliminated, in most cases a certain degree of safety risk must be accepted. In order to quantify expected accident costs before the fact, the potential consequences of an accident, and the probability of occurrence must be considered. Assessment of risk is made by combining the severity of consequence with the likelihood of occurrence in a matrix. Risks that fall into the "unacceptable" category (e.g., high severity and high probability) must be mitigated by some means to reduce the level of safety risk.

IEEE STD-1228-1994 Software Safety Plans prescribes industry best practices for conducting software safety hazard analyses to help ensure safety requirements and attributes are defined and specified for inclusion in software that commands, controls or monitors critical functions. When software is involved in a system, the development and design assurance of that software is often governed by DO-178B. The severity of consequence identified by the hazard analysis establishes the criticality level of the software. Software criticality levels range from A to E, corresponding to severities of Catastrophic to No Safety Effect. Higher levels of rigor are required for level A and B software and corresponding functional tasks and work products in the system safety domain are used as objective evidence of meeting safety criteria and requirements.

Recently a leading edge commercial standard was promulgated based on decades of proven system safety processes in DoD and NASA. ANSI/GEIA-STD-0010-2009 (Standard Best Practices for System Safety Program Development and Execution) is a demilitarized commercial best practice that uses proven hostistic, comprehensive and tailorable approaches for hazard prevention, elimination and control. It is centered around the hazard analysis and functional based safety process.

## **Severity definitions**

<b>Severity</b>	<b>Definition</b>
Catastrophic	<p>Results in multiple fatalities and/or loss of the system</p> <p>Reduces the capability of the system or the operator ability to cope with adverse conditions to the extent that there would be:</p> <ul style="list-style-type: none"> <li>• Large reduction in safety margin or functional capability</li> <li>• Crew physical distress/excessive workload such that operators cannot be relied upon to perform required tasks accurately or completely</li> </ul>
Hazardous	<ul style="list-style-type: none"> <li>• Serious or fatal injury to small number of occupants of aircraft (except operators)</li> <li>• Fatal injury to ground personnel and/or general public</li> </ul> <p>Reduces the capability of the system or the operators to cope with adverse operating conditions to the extent that there would be:</p> <ul style="list-style-type: none"> <li>• Significant reduction in safety margin or functional capability</li> <li>• Significant increase in operator workload</li> <li>• Conditions impairing operator efficiency or creating significant discomfort</li> <li>• Physical distress to occupants of aircraft (except operator)</li> </ul>
Major	<p>including injuries</p> <ul style="list-style-type: none"> <li>• Major occupational illness and/or major environmental</li> </ul>

damage, and/or major property damage

Does not significantly reduce system safety. Actions required by operators are well within their capabilities. Include:

- Minor
- Slight reduction in safety margin or functional capabilities
  - Slight increase in workload such as routine flight plan changes
  - Some physical discomfort to occupants or aircraft (except operators)
  - Minor occupational illness and/or minor environmental damage, and/or minor property damage

No Safety Effect      Has no effect on safety

### ***Likelihood of occurrence***

<b>Likelihood</b>	<b>Definition</b>
Probable	<ul style="list-style-type: none"><li>• Qualitative: Anticipated to occur one or more times during the entire system/operational life of an item.</li><li>• Quantitative: Probability of occurrence per operational hour is greater than <math>1 \times 10^{-5}</math></li></ul>
Remote	<ul style="list-style-type: none"><li>• Qualitative: Unlikely to occur to each item during its total life. May occur several times in the life of an entire system or fleet.</li><li>• Quantitative: Probability of occurrence per operational hour is less than <math>1 \times 10^{-5}</math>, but greater than <math>1 \times 10^{-7}</math></li></ul>
Extremely Remote	<ul style="list-style-type: none"><li>• Qualitative: Not anticipated to occur to each item during its total life. May occur a few times in the life of an entire system or fleet.</li><li>• Quantitative: Probability of occurrence per operational hour is less than <math>1 \times 10^{-7}</math> but greater than <math>1 \times 10^{-9}</math></li></ul>
Extremely Improbable	<ul style="list-style-type: none"><li>• Qualitative: So unlikely that it is not anticipated to occur during the entire operational life of an entire system or fleet.</li><li>• Quantitative: Probability of occurrence per operational hour is less than <math>1 \times 10^{-9}</math></li></ul>

## Chapter 1

# Risk Assessment

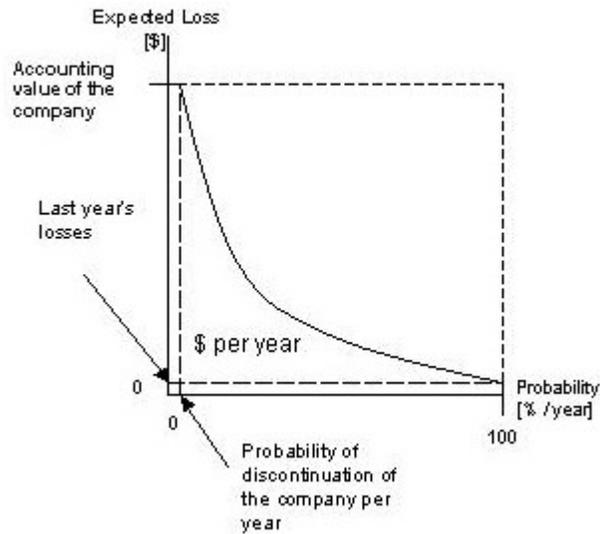
**Risk assessment** is a step in a risk management procedure. Risk assessment is the determination of quantitative or qualitative value of risk related to a concrete situation and a recognized threat (also called hazard). *Quantitative risk assessment* requires calculations of two components of risk:  $R$ , the magnitude of the potential loss  $L$ , and the probability  $p$ , that the loss will occur.

Methods may differ whether it is about general financial decisions or environmental, ecological, or public health risk assessment.

### ***Explanation***

Risk assessment consists in an objective evaluation of risk in which assumptions and uncertainties are clearly considered and presented. Part of the difficulty of risk management is that measurement of both of the quantities in which risk assessment is concerned - potential loss and probability of occurrence - can be very difficult to measure. The chance of error in the measurement of these two concepts is large. A risk with a large potential loss and a low probability of occurring is often treated differently from one with a low potential loss and a high likelihood of occurring. In theory, both are of nearly equal priority in dealing with first, but in practice it can be very difficult to manage when faced with the scarcity of resources, especially time, in which to conduct the risk management process. Expressed mathematically,

$$R_i = L_i p(L_i)$$
$$R_{total} = \sum_i L_i p(L_i)$$



Risk assessment from a financial point of view.

Financial decisions, such as insurance, express loss in terms of dollar amounts. When risk assessment is used for public health or environmental decisions, loss can be quantified in a common metric, such as a country's currency, or some numerical measure of a location's quality of life. For public health and environmental decisions, loss is simply a verbal description of the outcome, such as increased cancer incidence or incidence of birth defects. In that case, the "risk" is expressed as:

$$R_i = p(L_i)$$

If the risk estimate takes into account information on the number of individuals exposed, it is termed a "population risk" and is in units of expected increased cases per a time period. If the risk estimate does not take into account the number of individuals exposed, it is termed an "individual risk" and is in units of incidence rate per a time period. Population risks are of more use for cost/benefit analysis; individual risks are of more use for evaluating whether risks to individuals are "acceptable"....

### ***Risk assessment in public health***

In the context of public health, risk assessment is the process of quantifying the probability of a harmful effect to individuals or populations from certain human activities. In most countries, the use of specific chemicals, or the operations of specific facilities (e.g. power plants, manufacturing plants) is not allowed unless it can be shown that they do not increase the risk of death or illness above a specific threshold. For example, the American Food and Drug Administration (FDA) regulates food safety through risk assessment. The FDA required in 1973 that cancer-causing compounds must

not be present in meat at concentrations that would cause a cancer risk greater than 1 in a million lifetimes. The US Environmental Protection Agency provides basic information about environmental risk assessments for the public via its risk assessment portal.

## **How the risk is determined**

In the estimation of the risks, three or more steps are involved, requiring the inputs of different disciplines:

1. *Hazard Identification*, aims to determine the qualitative nature of the potential adverse consequences of the contaminant (chemical, radiation, noise, etc.) and the strength of the evidence it can have that effect. This is done, for chemical hazards, by drawing from the results of the sciences of toxicology and epidemiology. For other kinds of hazard, engineering or other disciplines are involved.
2. *Dose-Response Analysis*, is determining the relationship between dose and the probability or the incidence of effect (dose-response assessment). The complexity of this step in many contexts derives mainly from the need to extrapolate results from experimental animals (e.g. mouse, rat) to humans, and/or from high to lower doses. In addition, the differences between individuals due to genetics or other factors mean that the hazard may be higher for particular groups, called susceptible populations. An alternative to dose-response estimation is to determine an effect unlikely to yield observable effects, that is, a no effect concentration. In developing such a dose, to account for the largely unknown effects of animal to human extrapolations, increased variability in humans, or missing data, a prudent approach is often adopted by including safety factors in the estimate of the "safe" dose, typically a factor of 10 for each unknown step.
3. *Exposure Quantification*, aims to determine the amount of a contaminant (dose) that individuals and populations will receive. This is done by examining the results of the discipline of exposure assessment. As different location, lifestyles and other factors likely influence the amount of contaminant that is received, a range or distribution of possible values is generated in this step. Particular care is taken to determine the exposure of the susceptible population(s).

Finally, the results of the three steps above are then combined to produce an estimate of risk. Because of the different susceptibilities and exposures, this risk will vary within a population.

## **Small subpopulations**

When risks apply mainly to small subpopulations, there is uncertainty at which point intervention is necessary. What if a risk is very low for everyone but 0.1% of the population? A difference exists whether this 0.1% is represented by \*all infants younger than  $X$  days or \*recreational users of a particular product. If the risk is higher for a particular sub-population because of abnormal exposure rather than susceptibility, there is a potential to consider strategies to further reduce the exposure of that subgroup. If an identifiable sub-population is more susceptible due to inherent genetic or other factors,

there is a policy choice whether to set policies for protecting the general population that are protective of such groups (as is currently done for children when data exists, or is done under the Clean Air Act for populations such as asthmatics) or whether if the group is too small, or the costs too high. Sometimes, a more specific calculation can be applied whether it is more important to analyze each method specifically the changes of the risk assessment method in containing all problems that each of us people could replace.

### **Acceptable risk increase**

The idea of not increasing lifetime risk by more than one in a million has become common place in public health discourse and policy. How consensus settled on this particular figure is unclear. In some respects, this figure has the characteristics of a mythical number. In another sense, the figure provides a numerical basis for what to consider a negligible increase in risk. Some current environmental decision making allows some discretion to deem individual risks potentially "acceptable" if below one in ten thousand increased lifetime risk. Low risk criteria such as these do provide some protection for the case that individuals may be exposed to multiple chemicals (whether pollutants or food additives, or other chemicals). But both of these benchmarks are clearly small relative to the typical one in four lifetime risk of death by cancer (due to all causes combined) in developed countries. On the other hand, adoption of a zero-risk policy could be motivated by the fact that the 1 in a million policy still would cause the death of hundreds or thousands of people in a large enough population. In practice however, a true zero-risk is possible only with the suppression of the risk-causing activity.

More stringent requirements, or even the 1 in a million one, may not be technologically feasible at a given time, or so expensive as to render the risk-causing activity unsustainable, resulting in the optimal degree of intervention being a balance between risks vs. benefit. For example, it might well be that the emissions from hospital incinerators result in a certain number of deaths per year. However, this risk must be balanced against the available alternatives. In some unusual cases, there are significant public health risks, as well as economic costs, associated with all options. For example, there are risks associated with no incineration (with the potential risk for spread of infectious diseases) or even no hospitals. But, often further investigation identifies further options, such as separating noninfectious from infectious wastes, or air pollution controls on a medical incinerator, that provide a broad range of options of acceptable risk - though with varying practical implications and varying economic costs. Intelligent thought about a reasonably full set of options is essential. Thus, it is not unusual for there to be an iterative process between analysis, consideration of options, and then further analysis.

### ***Risk assessment in auditing***

In auditing, risk assessment is a very crucial stage before accepting an audit engagement. According to ISA315 *Understanding the Entity and its Environment and Assessing the Risks of Material Misstatement*, "the auditor should perform risk assessment procedures to obtain an understanding of the entity and its environment, including its internal

control."<evidence relating to the auditor's risk assessment of a material misstatement in the client's financial statements. Then, auditor obtains initial evidence regarding the classes of transactions at the client and the operating effectiveness of the client's internal controls. In auditing, audit risk includes inherent risk, control risk and detection risk.

### ***Risk assessment and human health***

There are many resources that provide health risk information. The National Library of Medicine provides risk assessment and regulation information tools for a varied audience. These include TOXNET (databases on hazardous chemicals, environmental health, and toxic releases), the Household Products Database (potential health effects of chemicals in over 10,000 common household products), and TOXMAP (maps of US Environmental Agency Superfund and Toxics Release Inventory data). The United States Environmental Protection Agency provides basic information about environmental risk assessments for the public.

### ***Risk assessment in information security***

IT risk assessment can be performed by a qualitative or quantitative approach, following different methodologies.

### ***Risk assessment in project management***

In project management, risk assessment is an integral part of the risk management plan, studying the probability, the impact, and the effect of every known risk on the project, as well as the corrective action to take should that risk occur.

### ***Risk assessment for megaprojects***

Megaprojects (sometimes also called "major programs") are extremely large-scale investment projects, typically costing more than US\$1 billion per project. Megaprojects include bridges, tunnels, highways, railways, airports, seaports, power plants, dams, wastewater projects, coastal flood protection, oil and natural gas extraction projects, public buildings, information technology systems, aerospace projects, and defence systems. Megaprojects have been shown to be particularly risky in terms of finance, safety, and social and environmental impacts. Risk assessment is therefore particularly pertinent for megaprojects and special methods and special education have been developed for such risk assessment.

### ***Quantitative risk assessment***

Quantitative risk assessments include a calculation of the single loss expectancy (SLE) of an asset. The single loss expectancy can be defined as the loss of value to asset based on a single security incident. The team then calculates the Annualized Rate of Occurrence (ARO) of the threat to the asset. The ARO is an estimate based on the data of how often a

threat would be successful in exploiting a vulnerability. From this information, the Annualized Loss Expectancy (ALE) can be calculated. The annualized loss expectancy is a calculation of the single loss expectancy multiplied by the annual rate of occurrence, or how much an organization could estimate to lose from an asset based on the risks, threats, and vulnerabilities. It then becomes possible from a financial perspective to justify expenditures to implement countermeasures to protect the asset.

### ***Risk assessment in software evolution***

Studies have shown that early parts of the system development cycle such as requirements and design specifications are especially prone to error. This effect is particularly notorious in projects involving multiple stakeholders with different points of view. Evolutionary software processes offer an iterative approach to requirement engineering to alleviate the problems of uncertainty, ambiguity and inconsistency inherent in software developments.

### ***Criticisms of quantitative risk assessment***

Barry Commoner, Brian Wynne and other critics have expressed concerns that risk assessment tends to be overly quantitative and reductive. For example, they argue that risk assessments ignore qualitative differences among risks. Some charge that assessments may drop out important non-quantifiable or inaccessible information, such as variations among the classes of people exposed to hazards. Furthermore, Commoner and O'Brien claim that quantitative approaches divert attention from precautionary or preventative measures. Others, like Nassim Nicholas Taleb consider risk managers little more than "blind users" of statistical tools and methods.

## Chapter 2

# Globally Harmonized System of Classification and Labelling of Chemicals

The **Globally Harmonized System of Classification and Labeling of Chemicals** or **GHS** is an internationally agreed upon system set to replace the various different classification and labeling standards used in different countries. The GHS will use consistent criteria for classification and labeling on a global level. Its development began at the United Nations Rio Conference in 1992, when the International Labour Organization (ILO), the Organisation for Economic Co-operation and Development (OECD), and various governments and stakeholders came together at the United Nations. It supersedes the relevant European Union and United States standards. The European Union has implemented the United Nations' GHS into EU law as the CLP Regulation.

### *History*

The Globally Harmonized System (GHS) for classification and labeling arose from the declaration at the 1992 Rio Conference on Environment and Development that “A globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, should be available if feasible, by the year 2000”. The goals of the GHS are to enhance protection of mankind and the environment, by:

- Providing an internationally comprehensible system for hazard communication.
- Providing a recognized framework for those countries without an existing system.
- Facilitating international trade in chemicals whose hazards have been properly assessed and identified on an international basis.
- Reducing the need for animal testing and evaluation of chemicals.

## ***What is it?***

The GHS is a common and consistent approach to defining and classifying hazards, and communicating hazard information on labels and safety data sheets (SDS). The GHS will cover all hazardous chemicals, which includes substances, products, mixtures, preparations, etc. It will provide an internationally agreed upon system of hazard classification and labeling. The target audiences include workers, consumers, transport workers, and emergency responders. Under this system, chemical substances and mixtures will be classified according to their physical, health, and environmental hazards. The GHS is not a regulation or a standard. Compliance with the GHS is voluntary for each country but companies in countries that do not adopt the GHS will be at a disadvantage when doing business internationally. The GHS document, otherwise known as “The Purple Book”, is a guidance document that establishes criteria and methods for hazard classification and communication. The GHS document provides countries with the regulatory framework to develop or modify existing programs.

## ***Why is GHS Needed?***

Currently many different countries have their own standards for chemical hazard classification and communication. The GHS is intended to replace these multiple systems with one uniform system that all parties have adopted. These existing systems may be similar in content and approach, but their differences are significant enough to require multiple classifications, labels and MSDS's for the same product when marketed in different countries. For example, a chemical may be considered toxic in one country, but not in another. These inconsistent systems impact both safety and business interests. Global businesses must comply with multiple regulations regarding hazard classification and labeling, which can be costly and time-consuming. Many underdeveloped countries have few, if any, requirements for communication of hazards. This system provides the infrastructure for these countries to implement a hazard classification and communication system. The United Nations Conference on the Environment and Development (UNCED) recognized that reliable management of chemicals is needed on a global basis to ensure the protection of all people. Given the extent of international trade in chemicals, and the potential impact on neighboring countries when controls are not implemented, it was determined that a worldwide approach was necessary. In the longer term, the GHS is expected to improve knowledge of the chronic health hazards of chemicals and encourage a move towards the elimination of hazardous chemicals, especially carcinogens, mutagens and reproductive toxins, or their replacement with less hazardous ones.

## ***Hazard Classification***

The GHS classification system is complex. The data used for classification may be obtained from tests, literature, and practical experience. The main elements of the hazard classification criteria are summarized below:

## Physical Hazards

Physical hazards are largely based on those of the United Nations Dangerous Goods System. These regulations and UN test methods can be found at the United Nations website at [. Some additions and changes were necessary since the scope of the GHS includes all target audiences.](#)

- **Explosives**, which are assigned to one of six subcategories depending on the type of hazard they present, as used in the UN Dangerous Goods System.
- A **Flammable Gas** is one that has a flammable range in air at 20 °C and a standard pressure of 101.3 kPa. Substances and mixtures of this hazard class are assigned to one of two hazard categories on the basis of the outcome of the test or calculation method.
- **Flammable Aerosols** should be considered for classification as Category 1 or Category 2 if they contain any component, which is classified as flammable according to the GHS criteria, that is, flammable liquids, flammable gases or flammable solids.
- **Oxidizing Gases** are any gas that may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does. Substances and mixtures of this hazard class are assigned to a single hazard category on the basis that, generally by providing oxygen, they cause or contribute to the combustion of other material more than air does.
- **Gases Under Pressure** are gases contained in a receptacle at a pressure not less than 280 Pa at 20 °C or as a refrigerated liquid. This endpoint covers four types of gases or gaseous mixtures to address the effects of sudden release of pressure or freezing which may lead to serious damage to people, property, or the environment independent of other hazards the gases may pose.
- A **Flammable Liquid** is a liquid with a flash point of not more than 93 °C. Substances and mixtures of this hazard class are assigned to one of four hazard categories on the basis of the flash point and boiling point.
- A **Flammable Solid** is one that is readily combustible or may cause or contribute to fire through friction. Readily combustible solids are powdered, granular, or pasty substances which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.
- **Self-Reactive Substances** are thermally unstable liquids or solids liable to undergo a strongly exothermic thermal decomposition even without participation of oxygen (air). This definition excludes materials classified under the GHS as explosive, organic peroxides or as oxidizing.
- A **Pyrophoric Liquid** is a liquid that, even in small quantities, is liable to ignite within five minutes after coming into contact with air. Substances and mixtures of this hazard class are assigned to a single hazard category on the basis of the outcome of the UN Test N.3.
- A **Pyrophoric Solid** is a solid that, even in small quantities, is liable to ignite within five minutes after coming into contact with air. Substances and mixtures of this hazard class are assigned to a single hazard category on the basis of the outcome of the UN Test N.2.

- **Self-Heating Substances** are solids or liquids, other than a pyrophoric substance, which, by reaction with air and without energy supply, is liable to self-heat. Substances and mixtures of this hazard class are assigned to one of two hazard categories on the basis of the outcome of the UN Test N.4.
- **Substances which on Contact with Water Emit Flammable Gases** are substances that, in contact with water, emit flammable gases are solids or liquids which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities. Substances and mixtures of this hazard class are assigned to one of three hazard categories on the basis of the outcome of UN Test N.5, which measures gas evolution and speed of evolution.
- **Oxidizing Liquids** are liquids that, while in it is not necessarily combustible, may, generally by yielding oxygen, cause or contribute to the combustion of other material. Substances and mixtures of this hazard class are assigned to one of three hazard categories on the basis of the outcome of UN Test O.2.
- **Oxidizing Solids** are solids that, while it is not necessarily combustible, may, generally by yielding oxygen, cause or contribute to the combustion of other material. Substances and mixtures of this hazard class are assigned to one of three hazard categories on the basis of the outcome of UN Test O.1.
- **Organic Peroxides** are organic liquids or solids that contain the bivalent -O-O- structure and may be considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures). Substances and mixtures of this hazard class are assigned to one of seven 'Types', A to G, on the basis of the outcome of the UN Test Series A to H.
- **Substances Corrosive to Metal** are substances or a mixtures that by chemical action will materially damage, or even destroy metals. These substances or mixtures are classified in a single hazard category on the basis of tests (Steel: ISO 9328 (II): 1991 - Steel type P235; Aluminum: ASTM G31-72 (1990) - non-clad types 7075-T6 or AZ5GU-T66). The GHS criteria are a corrosion rate on steel or aluminum surfaces exceeding 6.25 mm per year at a test temperature of 55 °C.

## Health Hazards

- **Acute Toxicity** includes five GHS categories from which the appropriate elements relevant to transport, consumer, worker and environment protection can be selected. Substances are assigned to one of the five toxicity categories on the basis of LD<sub>50</sub> (oral, dermal) or LC<sub>50</sub> (inhalation).
- **Skin Corrosion** means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours. Substances and mixtures in this hazard class are assigned to a single harmonized corrosion category.
- **Skin Irritation** means the production of reversible damage to the skin following the application of a test substance for up to 4 hours. Substances and mixtures in this hazard class are assigned to a single irritant category. For those authorities,

such as pesticide regulators, wanting more than one designation for skin irritation, an additional mild irritant category is provided.

- **Serious Eye Damage** means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the front surface of the eye, which is not fully reversible within 21 days of application. Substances and mixtures in this hazard class are assigned to a single harmonized category.
- **Eye Irritation** means changes in the eye following the application of a test substance to the front surface of the eye, which are fully reversible within 21 days of application. Substances and mixtures in this hazard class are assigned to a single harmonized hazard category. For authorities, such as pesticide regulators, wanting more than one designation for eye irritation, one of two subcategories can be selected, depending on whether the effects are reversible in 21 or 7 days.
- **Respiratory Sensitizer** means a substance that induces hypersensitivity of the airways following inhalation of the substance. Substances and mixtures in this hazard class are assigned to one hazard category.
- **Skin Sensitizer** means a substance that will induce an allergic response following skin contact. The definition for "skin sensitizer" is equivalent to "contact sensitizer". Substances and mixtures in this hazard class are assigned to one hazard category.
- **Germ Cell Mutagenicity** means an agent giving rise to an increased occurrence of mutations in populations of cells and/or organisms. Substances and mixtures in this hazard class are assigned to one of two hazard categories. Category 1 has two subcategories.
- **Carcinogenicity** means a chemical substance or a mixture of chemical substances that induce cancer or increase its incidence. Substances and mixtures in this hazard class are assigned to one of two hazard categories. Category 1 has two subcategories.
- **Reproductive Toxicity** includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in offspring. Substances and mixtures with reproductive and/or developmental effects are assigned to one of two hazard categories, 'known or presumed' and 'suspected'. Category 1 has two subcategories for reproductive and developmental effects. Materials, which cause concern for the health of breastfed children, have a separate category, Effects on or Via Lactation.
- **Target Organ Systemic Toxicity (TOST)** category distinguishes between single and repeated exposure for Target Organ Effects. All significant health effects, not otherwise specifically included in the GHS, that can impair function, both reversible and irreversible, immediate and/or delayed are included in the non-lethal target organ/systemic toxicity class (TOST). Narcotic effects and respiratory tract irritation are considered to be target organ systemic effects following a single exposure. Substances and mixtures of the single exposure target organ toxicity hazard class are assigned to one of three hazard categories. Substances and mixtures of the repeated exposure target organ toxicity hazard class are assigned to one of two hazard categories.

- **Aspiration Hazard** includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration. Aspiration is the entry of a liquid or solid directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system. Substances and mixtures of this hazard class are assigned to one of two hazard categories this hazard class on the basis of viscosity.

## Environmental Hazards

- **Acute Aquatic Toxicity** means the intrinsic property of a material to cause injury to an aquatic organism in a short-term exposure. Substances and mixtures of this hazard class are assigned to one of three toxicity categories on the basis of acute toxicity data: LC<sub>50</sub> (fish) or EC<sub>50</sub> (crustacean) or ErC<sub>50</sub> (for algae or other aquatic plants). In some regulatory systems these acute toxicity categories may be subdivided or extended for certain sectors.
- **Chronic Aquatic Toxicity** means the potential or actual properties of a material to cause adverse effects to aquatic organisms during exposures that are determined in relation to the lifecycle of the organism. Substances and mixtures in this hazard class are assigned to one of four toxicity categories on the basis of acute data and environmental fate data: LC<sub>50</sub> (fish) or EC<sub>50</sub> (crustacea) or ErC<sub>50</sub> (for algae or other aquatic plants) and degradation or bioaccumulation.

## Classification of Mixtures

The GHS approach to the classification of mixtures for health and environmental hazards is also complex. It uses a tiered approach and is dependent upon the amount of information available for the mixture itself and for its components. Principles that have been developed for the classification of mixtures, drawing on existing systems such as the European Union (EU) system for classification of preparations laid down in Directive 1999/45/EC. The process for the classification of mixtures is based on the following steps:

1. Where toxicological or ecotoxicological test data are available for the mixture itself, the classification of the mixture will be based on that data;
2. Where test data are not available for the mixture itself, then the appropriate bridging principles should be applied, which uses test data for components and/or similar mixtures;
3. If (1) test data are not available for the mixture itself, and (2) the bridging principles cannot be applied, then use the calculation or cutoff values described in the specific endpoint to classify the mixture.

## Testing requirements

The GHS document does not include testing requirements for substances or mixtures. In fact, one of the main goals of the GHS is to reduce the need for animal testing. The GHS criteria for determining health and environmental hazards are test method neutral,

allowing different approaches as long as they are scientifically sound and validated according to international procedures and criteria already referred to in existing systems. Test data already generated for the classification of chemicals under existing systems should be accepted when classifying these chemicals under the GHS, thereby avoiding duplicative testing and the unnecessary use of test animals. The GHS physical hazard criteria are linked to specific UN test methods. It is assumed that mixtures will be tested for physical hazards.

## ***Hazard communication***

After the substance or mixture has been classified according to the GHS criteria, the hazards need to be communicated. As with many existing systems, the communication methods incorporated in GHS include labels and MSDS's. The GHS attempts to standardize hazard communication so that the intended audience can better understand the hazards of the chemicals in use. The GHS has established guiding principles:

- The problem of trade secret or confidential business information has not been addressed within the GHS, except in general terms. For example, non-disclosure of confidential business information should not compromise the health and safety of users.
- Hazard communication should be available in more than one form (for example, placards, labels or MSDS's).
- Hazard communication should include hazard statements and precautionary statements.
- Hazard communication information should be easy to understand and standardized.
- Hazard communication phrases should be consistent with each other to reduce confusion.
- Hazard communication should take into account all existing research and any new evidence.

Comprehensibility is challenging for a single culture and language. Global harmonization has numerous complexities. Some factors that affected the work include:

- Different philosophies in existing systems on how and what should be communicated;
- Language differences around the world;
- Ability to translate phrases meaningfully;
- Ability to understand and appropriately respond to symbols/pictograms.

These factors were considered in developing the GHS communication tools. The GHS Purple Book includes a comprehensibility-testing instrument in Annex 6.

## GHS Label Elements



One of the new symbols

The standardized label elements included in the GHS are:

- **Symbols** (hazard pictograms): Convey health, physical and environmental hazard information, assigned to a GHS hazard class and category. Pictograms include the harmonized hazard symbols plus other graphic elements, such as borders, background patterns or colors that are intended to convey specific information. The symbols are similar to current EU symbols, with a few exceptions. A new hazard symbol featuring a white sprawling mass within a bust of a human is introduced. It is used for carcinogens, mutagens, reproductive toxicity, aspiration hazards, respiratory sensitizers and substances which have target organ toxicity. Also, harmful chemicals and irritants are marked with an exclamation mark,

replacing the European saltire. Pictograms will have a black symbol on a white background with a red diamond frame. For transport, pictograms will have the background, symbol and colors currently used in the *UN Recommendations on the Transport of Dangerous Goods*. Where a transport pictogram appears, the GHS pictogram for the same hazard should not appear.

- **Signal Words:** "Danger" or "Warning" will be used to emphasize hazards and indicate the relative level of severity of the hazard, assigned to a GHS hazard class and category. Some lower level hazard categories do not use signal words. Only one signal word corresponding to the class of the most severe hazard should be used on a label.
- **Hazard Statements:** Standard phrases assigned to a hazard class and category that describe the nature of the hazard. An appropriate statement for each GHS hazard should be included on the label for products possessing more than one hazard.

The additional label elements included in the GHS are:

- **Precautionary Statements:** Measures to minimize or prevent adverse effects. There are four types of precautionary statements covering: prevention, response in cases of accidental spillage or exposure, storage, and disposal. The precautionary statements have been linked to each GHS hazard statement and type of hazard.
- **Product Identifier** (ingredient disclosure): Name or number used for a hazardous product on a label or in the MSDS. The GHS label for a substance should include the chemical identity of the substance. For mixtures, the label should include the chemical identities of all ingredients that contribute to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitization, or Target Organ Systemic Toxicity (TOST), when these hazards appear on the label.
- **Supplier identification:** The name, address and telephone number should be provided on the label.
- **Supplemental information:** Non-harmonized information on the container of a hazardous product that is not required or specified under the GHS. Supplemental information may be used to provide further detail that does not contradict or cast doubt on the validity of the standardized hazard information.

## GHS Label Format

The GHS includes directions for application of the hazard communication elements on the label. In particular, it specifies for each hazard, and for each class within the hazard, what signal word, pictogram, and hazard statement should be used. The GHS hazard pictograms, signal words and hazard statements should be located together on the label. The actual label format or layout is not specified in the GHS. National authorities may choose to specify where information should appear on the label or allow supplier discretion. There has been discussion about the size of GHS pictograms and that a GHS pictogram might be confused with a transport pictogram or "diamond". Transport pictograms are different in appearance than the GHS pictograms. Annex 7 of the Purple

Book explains how the GHS pictograms are expected to be proportional to the size of the label text. So that generally the GHS pictograms would be smaller than the transport pictograms.

## **GHS Material Safety Data Sheet or Safety Data Sheet**

The safety data sheet (The GHS has dropped the word “material” from material safety data sheet. It will now be called the safety data sheet or SDS) is specifically aimed at use in the workplace. It should provide comprehensive information about the chemical product that allows employers and workers to obtain concise, relevant and accurate information that can be put in perspective with regard to the hazards, uses and risk management of the chemical product in the workplace. The SDS should contain 16 sections. While there were some differences in existing industry recommendations, and requirements of countries, there was widespread agreement on a 16 section SDS that includes the following headings in the order specified:

1. Identification
2. Hazard(s) identification
3. Composition/ information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure control/ personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information.

The primary difference between the GHS requirements in terms of headings and sections and the international industry recommendations is that sections 2 and 3 have been reversed in order. The GHS SDS headings, sequence and content are similar to the ISO, EU and ANSI MSDS/SDS requirements. The SDS should provide a clear description of the data used to identify the hazards.

### ***Training***

Current training procedures for Hazard Communication in the United States are more detailed than the GHS training recommendations. Therefore, educating employees on the updated chemical and product classifications and related pictograms, signal words, hazard statements and precautionary measures will represent the greatest training challenge. Training will be a key component of the overall GHS approach and should

incorporate information as it is introduced into the workplace. Employees and emergency responders will need to be trained on all new program elements, from hazard statements to pictograms. Bear in mind, if products are imported from countries that implement GHS prior to the United States and Canada, employee training may need to begin earlier than expected.

## ***Implementation***

The adoption of the GHS is expected to facilitate international trade by increasing consistency between the laws in different countries that currently have different hazard communication requirements. There is no set international implementation schedule for the GHS. The goal of the United Nations is broad international adoption by 2008. Different countries will require different time frames to update current regulations or implement new ones. In countries like the United States, for example, there are many facets of the regulatory system that will have to be modified in order to adopt and implement the GHS. Japan's Industrial Safety and Health Law has already been amended to reflect the GHS. In the United States, an Advanced Notice of Proposed Rulemaking was published in the Federal Register on September 12, 2006. The European Commission has published a legislative proposal to change the current system based on Directive 67/548/EEC to one based on the GHS: it is expected that the new regulation will be passed in 2009 and come into force between 2010 and 2015. Australia is well-advanced on preparing regulations to implement the GHS for industrial chemicals, with new regulations expected in 2012. The UN monitors international implementation status of the GHS, and publishes a summary of the current status.

## Chapter 3

# Behavior-Based Safety

**Behavior-based safety (BBS)** is the "application of science of behavior change to real world problems". BBS "focuses on what people do, analyzes why they do it, and then applies a research-supported intervention strategy to improve what people do". At its very core BBS is based on a larger scientific field called Organizational Behavior Analysis.

To be successful a BBS program must include all employees. This includes the CEO to the floor associates. To achieve changes in behavior, a change in policy, procedures and/or systems most assuredly will also need some change. Those changes cannot be done without buy-in and support from all involved in making those decisions.

BBS is not based on assumptions, personal feeling, and/or common knowledge. To be successful, the BBS program used must be based on scientific knowledge.

A good BBS program will consist of:

- Common goals – Both employee and managerial involvement in the process
- Definition of what is expected – Specifications of target behaviors derived from safety assessments
- Observational data collection
- Decisions about how best to proceed based on those data
- Feedback to associates being observed
- Review

All of the BBS programs reviewed included multilevel teams. Some programs use them in the assessment phase, some in observation and some in review. Some had all three areas using multilevel teams.

Behavior-based safety must also have attitude adjustment to be sustaining. It has been proven that "behavior influences attitude and attitude influences behavior". The goal

should be small gains over and over again; continuous growth. BBS is not a quick fix. It is a commitment.

There are numerous programs on how to implement behavior-based safety programs. They vary in price, detail and commitment. But the goal is always the same: eliminate injury. A review of all scientific publications on behavior-based safety since the mid 1970s to date shows that different approaches exert different effects. Focusing on workgroups, in static settings was demonstrated to be the most efficient at behavior change and injury reduction. Different configurations of the design elements also affects the Return on Investment, with one producing \$1.7 million, per 200,000 hours worked, while another loses \$2 million per 200,000 hours worked,

## ***History***

Behavior-based safety is a topic that has been around for a long time. BBS originated with the work of Herbert William Heinrich. In the 1930s, Heinrich, who worked for Traveler's Insurance Company, reviewed thousands of accident reports completed by supervisors and from these drew the conclusion that most accidents, illnesses and injuries in the workplace are directly attributable to "man-failures," or the unsafe actions of workers. Of the reports Heinrich reviewed, 73% classified the accidents as "man-failures"; Heinrich himself reclassified another 15% into that category, arriving at the still-cited finding that 88% of all accidents, injuries and illnesses are caused by worker errors.

Heinrich's data does not tell why the person did what they did to cause the accident, just that accident occurred. BBS programs delve into the acts that cause the accident. It delves into the work place; environment, equipment, procedures and attitudes.

Basic Organizational Behavior Analysis is what is used to identify the actions that put the associate in the risk position. Organizational Behavior Analysis has been done for 100 years. Directing the applied research to an organizational application specifically to safety has been going on for around 20 years.

Heinrich published work describing the results that he derived by evaluating the accidents from an extensive data base compiled by the insurance industry. He came to the conclusion that roughly 90% of all incidents are caused by human error. This conclusion became the foundation of what BBS has come to be today. BBS addresses the fact that there are additional reasons for injuries in the work place: environment, equipment, procedures and attitudes. Behavioral Science Technology (BST), pioneers in applying BBS processes, expanded on this work and identified the "working interface," the point where exposure to injury occurs.

The phrase "behavior-based safety" (BBS) was coined by Dr. E. Scott Geller of Safety Performance Solutions in 1979. It then became the catch phrase of the safety systems industry. One of his graduate students and coworkers, Dr. Josh Williams, distilled many

of these concepts in his guide "Keeping People Safe: The Human Dynamics of Injury Prevention."

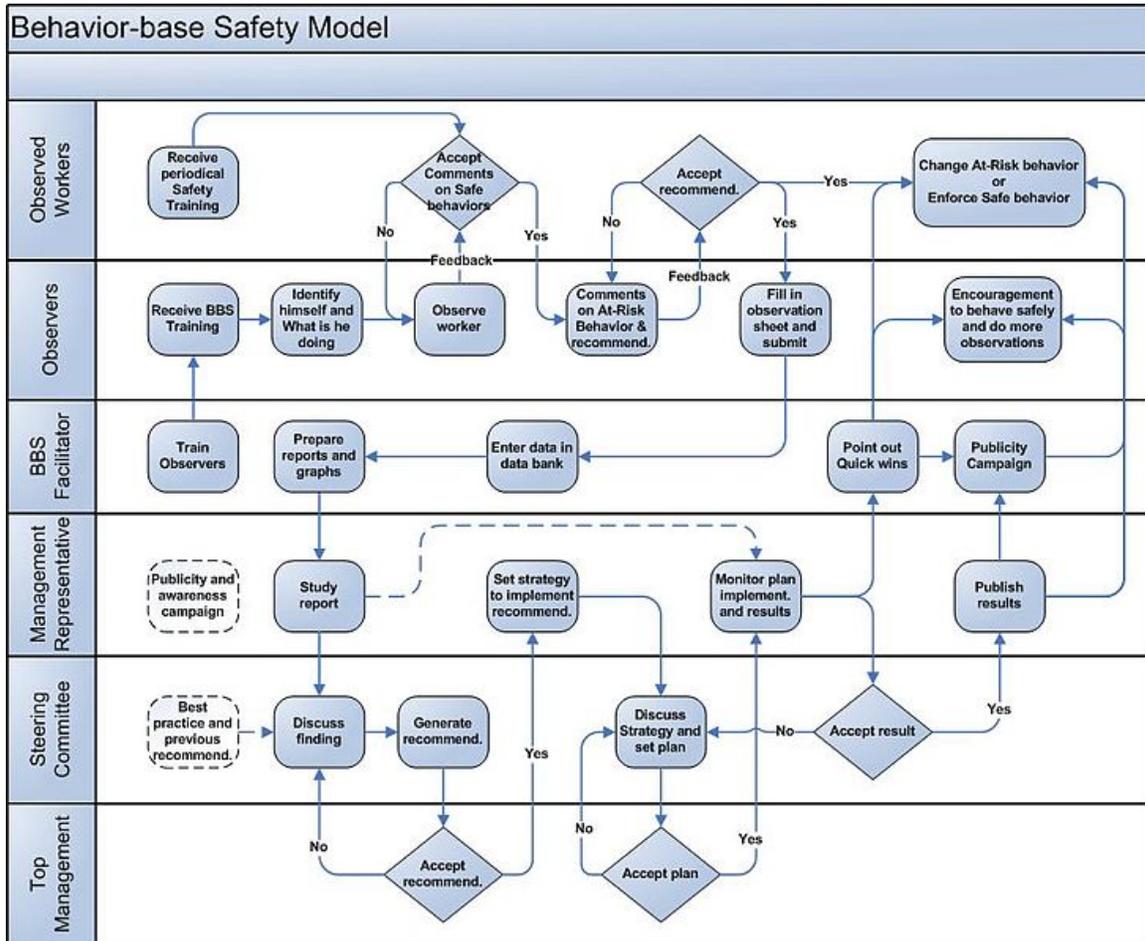
Traditionally BBS has been used in industrial settings. A new generation has found success using BBS in office/lab settings as well. More recent work has also applied this to MRSA in acute Intensive care wards in hospitals.

Dr. Luis López-Mena, Professor of Work Psychology at the University of Chile, has developed a BBS system, his PTAS Method (Psychological Techniques Applied to Safety). The PTAS Method has five steps:

- Identify target behavior
- Behavior measurement
- Functional analysis
- Intervention
- Evaluation and follow up

However, this approach is no different than most. Much of the current research is on how to allow the safety procedures to become institutionalized.

## How behavior-based safety works



BBS Model

### 1. Observation at site

The behavior-based safety (BBS) process depends on site observation. Site observation includes individual feedback, which is the most effective act in the BBS process. The observer meets the worker at site and introduces himself and the job he is going to do. There is no sneaking or spying in the process. The observer monitors the worker and notices his safe behaviors. He also monitors the at-risk behaviors the worker is putting himself in.

The observer starts his feedback by commending the safe behavior the worker was doing during his work. Then he explains, one-by-one, the at-risk behaviors the worker was doing. Then the observer asks the worker why he was putting himself at risk. For example, if the worker is welding a piece of metal and the sparks are flying in the worker's direction. The observer would then ask the worker why he was not wearing protective clothing, like a flame-retardant apron.

They both discuss the at-risk behaviors until the worker agrees to try the suggested recommendation made by the observer. The worker might be aware of his at-risk behavior or maybe not. The worker may be doing the at-risk behavior for a long time without hurting himself (negative consequences). The observer's job here is to highlight this behavior, then explain the associated negative consequences with this behavior.

The above discussion and agreement is the individual feedback which helps the worker to change his behavior. This feedback is considered as a form of reward since:

- The worker got commendable comments on his safe behavior.
- The worker understood his at-risk behavior without being reprimanded at site or reported to his superiors for further penalties.

At the end of the observation, the observer would fill in a checklist with the safe and at-risk behaviors he noticed along with the date, time and location of the observations. The worker's name or identification number are not noted in the checklist. Part of the checklist can be used to summarize the observation process and the discussion. The worker's comments and reasons for the at-risk behavior is recorded along with the suggested safe behavior. Recording this interaction is important for a later detailed analysis so feedback can be provided to both workers and management, to help identify the most appropriate corrective actions.

## 2. Data gathering and preliminary reports

Observation checklists are gathered and entered in electronic database. Reports are generated for BBS steering committee to analyze and recommend practical solutions. These reports flag out trends of at-risk behaviors and in which location they are taking place. Ideally, feedback reports are generated and given to the workers themselves in the different locations on a weekly basis.

## 3. Report analysis and recommendation

The steering committee is made up of high-level influential members and chaired by a Management Representative. The committee has periodical meetings to discuss and analyze BBS report findings. The committee then produces a set of recommendations to tackle workers' behaviors. Some of the recommendations would be as simple as providing Personal Protective Equipment (PPE) to workers in certain locations, or increase work force in another location. Some of the recommendations require site modification or costly machinery. Such recommendations are sent to top management for necessary approvals.

Implementing the recommendations would change the at-risk behaviors at the targeted location. Also the recommendations would eliminate hazards and risks caused by hardware or wrong design. Committee members devote time and effort

to discuss and analyze these reports in periodical meetings. These meetings are counted as part of the management commitment to the behavior process.

### ***Criticisms***

Donald J. Eckenfelder stated that he felt that "BBS has virtues but lasted too long and cost too much." He felt that it has been used incorrectly turning the process into a hindrance instead of a help. His analogy was "Water is essential to life: if we fill our lungs with it, it becomes poison." Some think that BBS has outlived its usefulness. In fact, some feel that BBS "isolates safety instead of integrating it." (But no examples were given.) It is felt that the continuous inspection is not causing attitude or behavior shift and once it is discontinued, all bad habits come back. (Again this could be true if the program doesn't include addressing attitude.)

In response to such claims from Unions and others, Prof. Dominic Cooper, of BSMS Inc., published an article based on a survey of 247 companies implementing behavior-based safety (or behavioral safety). This revealed that no evidence had been put forward to support these critical assertions. Rather, the evidence overwhelmingly points to positive outcomes. Interestingly, over 92% of respondents wanted to work in a company using behavior-based safety.

## Chapter 4

# Hazard Analysis and Critical Control Points

**Hazard Analysis Critical Control Point or HACCP** is a systematic preventive approach to food safety and pharmaceutical safety that addresses physical, chemical, and biological hazards as a means of prevention rather than finished product inspection. HACCP is used in the food industry to identify potential food safety hazards, so that key actions can be taken to reduce or eliminate the risk of the hazards being realized. The system is used at all stages of food production and preparation processes including packaging, distribution, etc. The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) say that their mandatory HACCP programs for juice and meat are an effective approach to food safety and protecting public health. Meat HACCP systems are regulated by the USDA, while seafood and juice are regulated by the FDA. The use of HACCP is currently voluntary in other food industries.

A forerunner to HACCP was developed in the form of production process monitoring during World War II because traditional "end of the pipe" testing was not an efficient way to ferret out artillery shells that would not explode. HACCP itself was conceived in the 1960s when the US National Aeronautics and Space Administration (NASA) asked Pillsbury to design and manufacture the first foods for space flights. Since then, HACCP has been recognized internationally as a logical tool for adapting traditional inspection methods to a modern, science-based, food safety system. Based on risk-assessment, HACCP plans allow both industry and government to allocate their resources efficiently in establishing and auditing safe food production practices. In 1994, the organization of *International HACCP Alliance* was established initially for the US meat and poultry industries to assist them with implementing HACCP and now its membership has been spread over other professional/industrial areas.

Hence, HACCP has been increasingly applied to industries other than food, such as cosmetics and pharmaceuticals. This method, which in effect seeks to plan out unsafe practices, differs from traditional "produce and test" quality control methods which are less successful and inappropriate for highly perishable foods. In the US, HACCP compliance is regulated by 21 CFR part 120 and 123. Similarly, FAO/WHO published a

guideline for all governments to handle the issue in small and less developed food businesses.

## **History**

On 4 October 1957, the Soviet Union launched Sputnik, the world's first satellite. American president Dwight D. Eisenhower responded by committing the United States to the space race. Eisenhower signed the National Aeronautics and Space Act on 29 July 1958 that created the National Aeronautics and Space Administration (NASA) to put an American satellite in orbit and to get a person in space.

Food played a critical part in the manned space program. The initial group involved in this were Herbert Hollander, Mary Klicka, and Hamed El-Bisi of the United States Army Laboratories in Natick, Massachusetts and Dr. Paul A. Lachance of the Manned Spacecraft Center (Johnson Space Center since February 1973) in Houston, Texas. Pillsbury joined the program as a contractor in 1959 with Howard E. Baumann representing the company as its lead scientist. The main goal was to produce food that would not crumble under zero gravity, but also be safe to eat. Lachance imposed strict microbial requirements, including pathogen limits (including *E. coli*, *Salmonella*, and *Clostridium botulinum*) on all foods destined for space travel. All personnel involved realized that traditional quality control methods would be inadequate because there would be so much product testing involved for actual product to be used. NASA own requirements for Critical Control Points (CCP) in engineering management would be used as a guide for food safety. CCP derived from Failure mode and effects analysis (FMEA) from NASA via the munitions industry to test weapon and engineering system reliability. Using that information, NASA and Pillsbury required contractors to identify "critical failure areas" and eliminate them from the system, a first in the food industry then. Baumann, a microbiologist by training, was so pleased with Pillsbury's experience in the space program that he advocated for his company to adopt what would become HACCP at Pillsbury.

Soon thereafter, Pillsbury was confronted with a food safety issue of its own when glass was found contaminated in farina, a cereal commonly used in infant food. Baumann's leadership promoted HACCP in Pillsbury for producing commercial foods, and applied to its own food production. This led to a panel discussion at the 1971 National Conference on Food Protection that included examining CCPs and Good Manufacturing Practices in producing safe foods. Several botulism cases were attributed to under-processed low-acid canned foods in 1970-71. The United States Food and Drug Administration (FDA) asked Pillsbury to organize and conduct a training program on the inspection of canned foods for FDA inspectors. This 21 day program was first held in September 1972 with 11 days of classroom lecture and 10 days of canning plant evaluations. Canned food regulations (21 CFR 108, 21 CFR 110, 21 CFR 113, and 21 CFR 114) were first published in 1973. Pillsbury's training program to the FDA in 1972, titled "Food Safety through the Hazard Analysis and Critical Control Point System", was the first time that HACCP was used.

HACCP was initially set on three principles, now shown as principles one, two, and four in the section below. Pillsbury quickly adopted two more principles, numbers three and five, to its own company in 1975. It was further supported by the National Academy of Sciences (NAS) that governmental inspections by the FDA go from reviewing plant records to compliance with its HACCP system. A second proposal by the NAS led to the development of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in 1987. NACMCF was initially responsible for defining HACCP's systems and guidelines for its application and were coordinated with the Codex Committee for Food Hygiene, that led to reports starting in 1992 and further harmonization in 1997. By 1997, the seven HACCP principles listed below became the standard. A year earlier, the American Society for Quality offered their first certifications for HACCP Auditors. (First known as Certified Quality Auditor-HACCP, they were changed to Certified HACCP Auditor (CHA) in 2004.

HACCP expanded in all realms of the food industry, going into meat, poultry, seafood, dairy, and has spread now from the farm to the fork.

### ***The HACCP seven principles***

**Principle 1: Conduct a hazard analysis.** – Plans determine the food safety hazards and identify the preventive measures the plan can apply to control these hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

**Principle 2: Identify critical control points.** – A Critical Control Point (CCP) is a point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

**Principle 3: Establish critical limits for each critical control point.** – A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.

**Principle 4: Establish critical control point monitoring requirements.** – Monitoring activities are necessary to ensure that the process is under control at each critical control point. In the United States, the FSIS is requiring that each monitoring procedure and its frequency be listed in the HACCP plan.

**Principle 5: Establish corrective actions.** – These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

**Principle 6: Establish record keeping procedures.** – The HACCP regulation requires that all plants maintain certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

**Principle 7: Establish procedures for ensuring the HACCP system is working as intended.** – Validation ensures that the plants do what they were designed to do; that is, they are successful in ensuring the production of a safe product. Plants will be required to validate their own HACCP plans. FSIS will not approve HACCP plans in advance, but will review them for conformance with the final rule.

Verification ensures the HACCP plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits and microbial sampling and analysis. FSIS is requiring that the HACCP plan include verification tasks to be performed by plant personnel. Verification tasks would also be performed by FSIS inspectors. Both FSIS and industry will undertake microbial testing as one of several verification activities.

Verification also includes 'validation' – the process of finding evidence for the accuracy of the HACCP system (e.g. scientific evidence for critical limitations).

## ***Standards***

The seven HACCP principles are included in the international standard ISO 22000 FSMS 2005. This standard is a complete food safety and quality management system incorporating the elements of prerequisite programmes (GMP & SSOP), HACCP and the quality management system, which together form an organization's Total Quality Management system.

## ***HACCP training***

HACCP management system trainings are only offered by several commercial enthusiasts. However, ASQ does provide Trained HACCP Auditor (CHA) exam to individuals seeking the professional training. In the UK the Chartered Institute of Environmental Health (CIEH) offer a HACCP for Food Manufacturing qualification accredited by the QCA (Qualifications and Curriculum Authority).

## ***HACCP Application***

### **Applied range**

It can apply to several food categories; sea food, bulk milk production line, Bulk Cream and Butter Production Line, animal meat industry, Organic Chemical Contaminants in Food, Corn Curl Manufacturing Plant and etc.

## **USA**

- Fish and fishery products
- Fresh-cut produces
- Juice and nectary products
- Food outlets
- Meat and poultry products
- School food and services

### ***HACCP Implementation***

It involves monitoring, verifying and validating of the daily work that is compliant with regulatory requirements in all stages all the time. The differences among those three types of work are given by Saskatchewan Agriculture and Food.

### ***HACCP Versus ISO 22000***

ISO 22000 is the new standard bound to replace HACCP on issues related to food safety. Although several companies, especially the big ones, have either implemented or are on the point of implementing ISO 22000, there are many others which are rather timid and/or reluctant to implement it. The main reason behind that is the lack of information and the fear that the new standard is too demanding in terms of bureaucratic work, from abstract of case study.

## Chapter 5

# Hazard Symbol



The skull and crossbones, a common symbol for poison and other sources of lethal danger.

**Hazard symbols** are recognizable symbols designed to warn about hazardous materials or locations. The use of hazard symbols is often regulated by law and directed by standards organizations. Hazard symbols may appear with different colors, backgrounds, borders and supplemental information in order to signify the type of hazard.

## Types of hazard symbols

Name	Symbol	Unicode	Image
Toxic sign		U+2620	
Caution sign		U+2621	
Radiation sign		U+2622	
Ionizing radiation sign	?	?	
Non-ionizing radiation sign	?	?	
Food irradiation symbol	?	?	
Biohazard sign		U+2623	
Warning sign		U+26A0	
High voltage sign		U+26A1	
Magnetic field symbol	?	?	

Chemical weapon symbol

?

?



Laser hazard sign

?

?



Optical radiation

?

?



Tsunami hazard sign

?

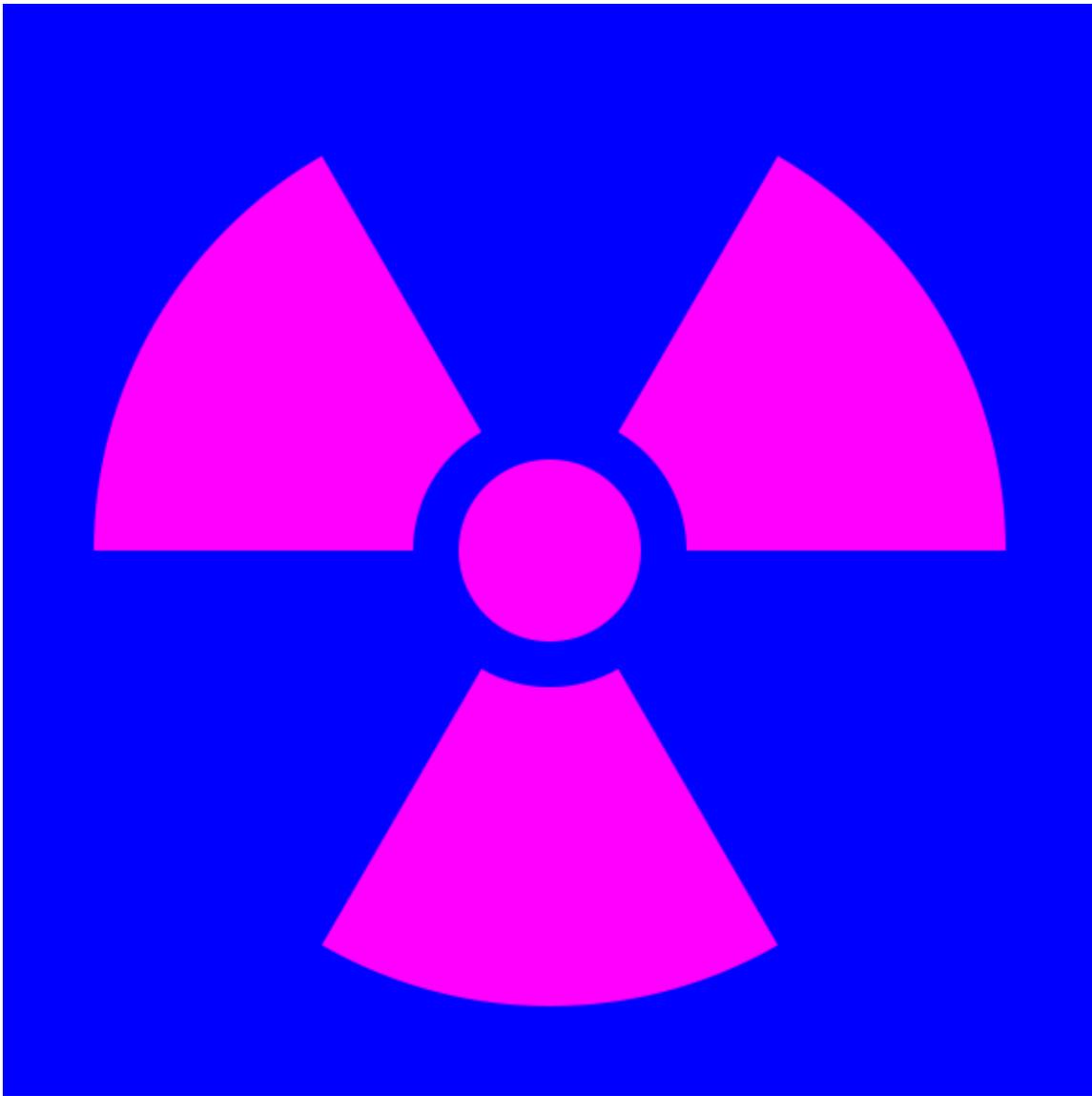
?



*Radioactive sign*



Current trefoil symbol



The early radioactive trefoil (1946)

The international radiation symbol (also known as trefoil) first appeared in 1946, at the University of California, Berkeley Radiation Laboratory. At the time, it was rendered as magenta, and was set on a blue background. The modern version is black against a yellow background, and it is drawn with a central circle of radius  $R$ , an internal radius of  $1.5R$  and an external radius of  $5R$  for the blades, which are separated from each other by  $60^\circ$ .



The new ISO 21482 radiation symbol

On February 15, 2007, the IAEA and the ISO announced this new ionizing radiation symbol to supplement the traditional trefoil symbol. The new symbol is aimed at alerting anyone, anywhere to the potential dangers of being close to a large source of ionizing radiation. Experts have felt that the trefoil symbol had little intuitive value and was less likely to be recognized by those not educated in its significance. According to the IAEA, in a survey conducted at an international school, many children mistook the trefoil for a non-threatening propeller. Hence, the Agency, along with the International Organization for Standardization has devised this symbol for sealed radiation sources. It depicts, on a red background, a black colored trefoil radiating waves, a skull and crossbones, and a person running away from the scene. The radiating trefoil suggests the presence of radiation and the red background and skull and crossbones warn of the danger. The person running away from the scene suggests the action of avoiding the labeled material. The symbol had been tested in countries with different population of varying groups, ages, and educational backgrounds to ensure that it clearly conveys the message “danger: stay away”. The new symbol is not intended to be generally visible, but appear on device internals housing radiation sources so that if someone attempts to disassemble a device it provides an explicit warning not to proceed any further.

## **Biohazard sign**



Biohazard symbol used since 1966

Developed by the Dow Chemical Company in 1966 for their containment products.

According to Charles Baldwin, an environmental-health engineer who contributed to its development: "We wanted something that was memorable but meaningless, so we could educate people as to what it means." In an article in *Science* in 1967, the symbol was presented as the new standard for all biological hazards ("biohazards"). The article explained that over 40 symbols were drawn up by Dow artists, and all of the symbols investigated had to meet a number of criteria: "(i) striking in form in order to draw immediate attention; (ii) unique and unambiguous, in order not to be confused with symbols used for other purposes; (iii) quickly recognizable and easily recalled; (iv) easily stenciled; (v) symmetrical, in order to appear identical from all angles of approach; and (vi) acceptable to groups of varying ethnic backgrounds." The chosen scored the best on nationwide testing for memorability.

It is used in the labeling of biological materials that carry a significant health risk, including viral samples and used hypodermic needles.

### **Drawing**

All parts of the biohazard sign can be drawn with a compass and straightedge. The basic outline of the symbol is a plain trefoil, which is three circles overlapping each other equally like in a triple venn diagram with the overlapping parts erased. The diameter of the overlapping part is equal to half the radius of the three circles. Then three inner circles are drawn in with  $\frac{2}{3}$  radius of the original circles so that it is tangent to the

outside three overlapping circles. A tiny circle in center has a diameter  $\frac{1}{2}$  of the radius of the three inner circle, and arcs are erased at  $90^\circ$ ,  $210^\circ$ ,  $330^\circ$ . The arcs of the inner circles and the tiny circle are connected by a line. Finally, the ring under is drawn from the distance to the perimeter of the equilateral triangle that forms between the centers of the three intersecting circles. An outer circle of the ring under is drawn and finally enclosed with the arcs from the center of the inner circles with a shorter radius from the inner circles.

### ***Poison sign***



Skull and crossbones

The skull-and-crossbones symbol, consisting of a human skull and two bones crossed together under the skull, is today generally used as a warning of danger, particularly in regard to poisonous substances.

The symbol, or some variation thereof, specifically with the bones (or swords) below the skull, was also featured on the Jolly Roger, the traditional flag of European and American pirates. It is also used by Skull and Bones, a secret society at Yale University, as well as the international male collegiate fraternity Phi Kappa Sigma. It is also part of the WHMIS home symbols placed on containers to confirm that the substance inside is dangerous in a way.

In the United States, due to concerns that the skull and bones symbol's association with pirates encourages children to play with toxic materials, the Mr. Yuk symbol is also used to denote poison.

## ***Warning sign***



German road warning sign

On warning signs, an exclamation mark is often used to draw attention to a warning of danger, hazards, and the unexpected. In Europe, this type of sign is used if there are no other appropriate signs to denote a hazard. When used in traffic signs a plate describing the hazard must be present. On an upright sign it is usually mounted under the exclamation mark.

**Chemical hazard**



NFPA 704 standard hazard sticker or placard.



European hazard sign, meaning *highly flammable* (33) - *gasoline* (1203)

A **chemical hazard label** is a pictogram applied to containers of dangerous chemical compounds to indicate the specific risk, and thus the required precautions. There are several systems of labels.

The U.S.-based National Fire Protection Association (NFPA) has a standard NFPA 704 using a diamond with four colored sections each with a number indicating severity 0-4 (0 for no hazard, 4 indicates a severe hazard). The red section denotes flammability. The blue section denotes health risks. Yellow represents reactivity (tendency to explode). The white section denotes special hazard information. This label is used primarily in the USA.

In Europe, another standard is used, as fixed in the European Agreement concerning the International Carriage of Dangerous Goods by Road. Vehicles carrying dangerous goods have to be fitted with orange signs, where the lower number identifies the substance, while the upper number is a key for the threat it may pose.

### ***Non-standard warning signs***



High voltage sign on a fence around the Beromünster Reserve Broadcasting Tower  
*English:* When you climb over the fence, you are in danger of death! The tower and the cables are high voltage!

A large number of warning signs of non-standard designs, such as the one on the right at the Beromünster Reserve Broadcasting Tower, are in use around the world.

## Chapter 6

# Job Safety Analysis

Job Safety Analysis (JSA), also known as Job Hazard Analysis (JHA), Activity Hazard Analysis (AHA) or Risk Assessment (RA), is a safety management tool in which the risks or hazards of a specific job in the workplace are identified, and then measures to eliminate or control those hazards are determined and implemented. More specifically, a job safety analysis is a process of systematically evaluating certain jobs, tasks, processes or procedures and eliminating or reducing the risks or hazards to as low as reasonably practical (ALARP) in order to protect workers from injury or illness. The JSA process is documented and the JSA document is used in the workplace or at the job site to guide workers in safe job performance. The JSA document is also a living document that is adjusted as conditions warrant.

The JSA process begins with identification of the potential hazards or risks associated with a particular job. Once the hazards are understood, the consequences of those hazards are then identified, followed by control measures to eliminate or mitigate the hazards. A more detailed JSA can be performed by breaking the job into steps and identifying specific hazards and control measures for each job step, providing the worker with a documented set of safe job procedures. Some JSA processes also include a risk assessment that lists the probability of each hazard occurring and the severity of the consequences, as well as the effectiveness of the control measures. The U.S. Army Corps of Engineers uses a risk assessment code (RAC) to analyze the level of risk associated with each job step.

The end result of a JSA is an easy to understand document that can be shared with workers as part of pre-job and safety meetings, and/or included as part of worker job descriptions. The JSA process can be used to help refine safe work procedures described in safety manuals or standard operating procedures, and the JSA document can serve as a useful tool in training new employees.

It is important to remember that a JSA is not simply a piece of paper; it is a process. Workers and management need to understand that a piece of paper will not make the job safe. Rather, workers and management must understand the risks and hazards associated with the job and know how to utilize the chosen controls in such a way as to eliminate or mitigate those risks. The JSA documents the decisions of this process.

## **WHAT TYPES OF JOBS NEED JSA?**

Many different types of jobs can benefit from a JSA, and JSAs are used across many different industries. In determining which jobs may need a JSA more urgently than others, priority should go to the following:

- Jobs with the highest injury or illness rates
- Jobs with the potential to cause severe or disabling injuries or illnesses, even if these is no history of previous accidents
- Jobs in which one simple human error could lead to a severe accident or injury
- Jobs that are new to your operation or have undergone changes in processes and procedures
- Jobs complex enough to require written instructions

## **WHY IS JSA IMPORTANT?**

Many workers are injured and killed at the workplace every day in countries all around the world, both in industrialized and non-industrialized countries. Protecting safety and health is critical to employee lives, jobs and business. Systematically looking at workplace operations, establishing proper job procedures and ensuring all employees are properly trained can help mitigate and prevent workplace injuries and illnesses. This is also likely to result in not only fewer worker injuries and illnesses, but also safer and more effective work methods, reduced workers' legal claims, increased productivity and fewer injury and lost time costs.

## **JSA as a leading indicator**

There is a growing trend among companies today to go beyond measurement of past safety performance and incident reports in developing their safety programs, and move into more proactive measurements of safety. Measurement of past incidents, successes and failures happens after the fact and is considered a “lagging” indicator. Measurement of future performance, or commitment to tangible goals, is considered a “leading” indicator. Performing a job safety analysis (JSA) can help workers and management identify potential hazards before they occur, and implement corrections so that they do not occur. Setting tangible goals to perform safety analyses of all jobs, or to correct all hazards so that they reach a specific minimal level of risk are other examples of using leading indicators to drive a safety program, as opposed to lagging indicators, which measure past performance.

## **JSA use in incident investigation**

In the event of an incident, documentation of the job safety analysis is critical to the team investigating the incident. By reviewing the process and understanding the hazards, controls, job steps and safe practices defined and implemented, incident investigators can gain valuable insight, leading to a better incident investigation, and in turn, better process, safer controls and safer work practices. The JSA document may also be helpful in event of legal remedies sought by aggrieved parties, as it provides a record of how the job is supposed to be performed safely, and the workers who signed off on it.

## ***TERMS***

### **What is a hazard?**

A hazard is the potential for harm. If left uncontrolled, a hazard could result in injury or harm. A hazard can be a physical object, chemical, noise, radiation, extreme heat or cold, electrical energy or anything else that has the potential to cause harm.

### **What is a control?**

A control is anything that will help to “control” the hazard by either preventing it from occurring or minimizing its impact if it does occur. If a hazard cannot be eliminated, steps should be taken so that the consequences of the hazard are as low as reasonably practical (ALARP).

If a workplace hazard cannot be eliminated or replaced with a non-hazardous substitution, it is necessary to implement hazard controls in order to protect the worker.

Controls can be categorized into three main types: engineering (altering the hazard or access to the hazard), administrative (altering the way in which the job is performed) and personal protective equipment, or PPE (altering the worker and his/her contact with the hazard). The U.S. Occupational Safety and Health Administration (OSHA) echoes the sentiments of many health and safety professionals when it states, “the most effective controls are engineering controls that physically change a machine or work environment to prevent employee exposure to the hazard. The more reliable or less likely a hazard control can be circumvented, the better. If this is not feasible, administrative controls may be appropriate. The generally accepted hierarchy for controls is engineering controls first, administrative controls second and PPE controls third.

### **Engineering Controls**

The U.S. National Institute for Occupational Health and Safety (NIOSH), a division of the Centers for Disease Control and Prevention (CDC) describes the use of engineering controls as being to, “remove a hazard or place a barrier between the worker and the

hazard". Examples of engineering controls include machine guards on mechanical blades/saws, ventilation systems to control fumes, wetting systems to control dust, circuit breakers and automatic shutoff switches on tanks and high pressure systems.

## **Administrative Controls**

If a hazard cannot be eliminated or minimized to an acceptable risk level by using engineering controls, administrative controls should be considered. Administrative controls change how a worker interacts with the hazard by setting out recommended policies and procedures to minimize worker contact with the hazard. Examples of administrative controls include developing a step by step procedure for performing the job safely, altering worker schedules to a time of day when the hazard is less likely to occur and designing policies such as a buddy-system or lockout/tagout system (which then becomes an engineering control once the system is shutdown). Required specialized training and permits are also often included in the "administrative controls" category.

## **Personal Protective Equipment (PPE) Controls**

If a hazard cannot be eliminated or minimized to an acceptable risk level by using engineering or administrative controls, steps should be taken to protect the worker as he or she interacts with the hazard by using protective clothing or equipment, also known as PPE. Examples of PPE include steel toed shoes, long pants, hard hat, high visibility reflective safety vest, face shield, tyvek suit, respirator and ear plugs.

## **PROCESS**

### **Who should conduct/create the JSA?**

Often, employers, foremen, supervisors and health and safety professionals conduct job safety analyses, which are then reviewed with and/or by workers performing the job. At other times, workers may discover a task on the job site which does not have a written JSA, and may conduct their own JSA on the job site before beginning the task.

### **How do I conduct/create a JSA?**

1. Involve your employees. It is very important to involve your employees in the hazard analysis process. They have a unique understanding of the job, and this knowledge is invaluable for finding hazards. Involving employees will help minimize oversights, ensure a quality analysis, and get workers to "buy in" to the solutions because they will share ownership in their safety and health program.
2. Review your accident history. Review with your employees your worksite's history of accidents and occupational illnesses that needed treatment, losses that required repair or replacement, and any "near misses" -- events in which an accident or loss did not occur, but could have. These events are indicators that the existing hazard controls (if any) may not be adequate and deserve more scrutiny.

3. Conduct a preliminary job review. Discuss with your employees the hazards they know exist in their current work and surroundings. Brainstorm with them for ideas to eliminate or control those hazards. **If any hazards exist that pose an immediate danger to a worker's life or health, take immediate action to protect the worker.** Any problems that can be corrected easily should be corrected as soon as possible. Do not wait to complete your job safety analysis. This will demonstrate your commitment to safety and health and enable you to focus on the hazards and jobs that need more study because of their complexity. For those hazards determined to present unacceptable risks, evaluate types of hazard controls.
4. List, rank, and set priorities for hazardous jobs. List jobs with hazards that present unacceptable risks, and rank them based on those most likely to occur and those with the most severe consequences. These jobs should be your first priority for analysis.
5. Outline the steps or tasks. Nearly every job can be broken down into job tasks or steps. When beginning a job safety analysis, watch the employee perform the job and list each step as the employee takes it. Be sure to record enough information to describe each job action without getting overly detailed. Avoid making the breakdown of steps so detailed that it becomes unnecessarily long or so broad that it does not include basic steps. You may find it valuable to get input from other workers who have performed the same job. Later, review the job steps with the employee to make sure you have not omitted something. Point out that you are evaluating the job itself, not the employee's job performance. Include the employee in all phases of the analysis -- from reviewing the job steps and procedures to discussing uncontrolled hazards and recommended solutions.

Be sure to document your findings in order to create a written record of your JSA.

Sometimes, in conducting a job safety analysis, it may be helpful to photograph or videotape the worker performing the job. These visual records can be handy references when doing a more detailed analysis of the work. Management and workers may also find it useful to assign a probability and severity ranking to each hazard in the job, denoting how likely – or probable – the hazard is to occur, and the severity of the consequences should it occur.

It is important to remember that the JSA should be performed prior to the start of work, updated as conditions change and reviewed periodically to ensure its accuracy. Many organizations perform and document their JSAs a day or so in advance, and then review them with workers that morning, prior to start of work. This helps ensure that they have taken the time to thoroughly analyze for hazards or risks, and have the appropriate controls in place to eliminate or minimize those hazards before arriving at the job site.

When conditions such as changes in job requirements, site conditions (e.g., weather), manpower or equipment operations (e.g., malfunctions, new equipment) present themselves, it is important to stop and re-analyze the job for potential new hazards created by these changes. New controlling measures should then be put in place to

eliminate or minimize the new hazard. If new controls cannot be implemented on the job to reduce the hazard to an acceptable risk level or ALARP, new engineering and administrative controls may need to be devised by job management or supervisors before returning to work.

## **How do I identify workplace hazards?**

A job safety analysis is an exercise in detective work. Your goal is to discover the following:

- What can go wrong?
- What are the consequences?
- How could the hazard arise?
- What are other contributing factors?
- How likely is it that the hazard will occur?

To make your job safety analysis useful, document the answers to these questions in a consistent manner. Describing a hazard in this way helps to ensure that your efforts to eliminate the hazard and implement hazard controls help target the most important contributors to the hazard.

Good hazard scenarios describe:

- Where it is happening (environment),
- To whom or what it is happening (exposure),
- What precipitates the hazard (trigger),
- The outcome that would occur should it happen (consequence), and
- Any other contributing factors?

## **Example Scenario**

Rarely is a hazard a simple case of one singular cause resulting in one singular effect. More frequently, many contributing factors tend to line up in a certain way to create the hazard. Here is an example of a hazard scenario:

In the metal shop (environment), snags in a machine are periodically encountered and need be cleared (trigger). The worker uses his hand (exposure) to clear the snag from a rotating pulley.

To perform a job safety analysis, you would ask:

- What can go wrong? The worker's hand could come into contact with a rotating object that "catches" it and pulls it into the machine.
- What are the consequences? The worker could receive a severe injury or lose fingers or hand.

- How could it happen? The accident could happen as a result of the worker trying to clear a snag during operations or as part of a maintenance activity while the pulley is operating. Obviously, this hazard scenario could not occur if the pulley is not rotating.
- What are other contributing factors? Because this hazard occurs very quickly, it does not give the worker much opportunity to recover or prevent it once his hand comes into contact with the pulley. This is an important contributing factor to note, because it helps you determine the severity and likelihood of the accident when selecting appropriate hazard controls.
- How likely is it that the hazard will occur? In the example, the likelihood that the hazard will occur is high because there is no guard preventing contact, and the operation is performed while the machine is running. Other factors to consider include past "near-misses" or actual cases, which show that the likelihood of recurrence is high, and if the pulley is exposed and easily accessible, also contributing to a high likelihood of occurrence. By following the steps in this example, you can organize your hazard analysis activities.
- What can be done to eliminate or minimize the hazard? In the example, we see that the rotating pulley is a hazard to the worker's hand. One way we could "control" this hazard is to install a machine guard to provide a barrier between the worker's hand and the rotating pulley. This is an engineering control. We could also implement an administrative control. Issuing a policy that requires the worker to power off the machine any time there is a snag would be an example of an administrative control. This will prevent the worker's hand from making contact with the pulley while it is rotating.

Our JSA for this scenario would include a description of the job the worker is performing (grinding metal), the types of hazards the worker could encounter (including the example above, as well as any other hazards that could occur) and the different ways in which those potential hazards will be eliminated or minimized.

Practical questions you might ask to help identify potential hazards include:

- Can any body part get caught in or between objects?
- Do tools, machines or equipment present any hazards?
- Can the worker make harmful contact with moving objects?
- Can the worker slip, trip or fall?
- Can the worker suffer strain from lifting, pushing or pulling?
- Is the worker exposed to extreme heat or cold?
- Is excessive noise or vibration a problem?
- Is there a danger from falling objects?
- Is lighting a problem?
- Can weather conditions affect safety?
- Is harmful radiation a possibility?
- Can contact be made with hot, toxic or caustic substances?
- Are there dusts, fumes, mists or vapors in the air?
- Can the worker make plant, insect or animal contact?

- Can any foreign object contact the eyes?

## **OTHER FORMATS**

### **USACE AHA format**

For U.S. Army Corps of Engineers (USACE) jobs, an Activity Hazard Analysis (AHA) including a specific equipment, equipment inspection and training section, as well as a risk assessment code (RAC) describing the level of probability and severity of the risk associated with each job step, is often required.

## **COUNTRIES**

### **AUSTRALIA**

“Safe Work Australia is an independent statutory agency with primary responsibility to improve occupational health and safety and workers' compensation arrangements across Australia.”

### **CANADA**

“The Canadian Centre for Occupational Health and Safety (CCOHS) has a vision: the elimination of work-related illnesses and injuries. We serve Canadians - and the world - with credible and relevant tools and resources to improve workplace health and safety programs. We encourage you to join us in creating a work world without pain, loss or tragedy. We believe that all Canadians have a fundamental right to a healthy and safe working environment. Through our programs, services, knowledge, commitment, and action, CCOHS will continue its efforts to advance health and safety in the workplace.”

### **UNITED STATES OF AMERICA**

“With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

“OSHA is part of the United States Department of Labor. The administrator for OSHA is the Assistant Secretary of Labor for Occupational Safety and Health. OSHA's administrator answers to the Secretary of Labor, who is a member of the cabinet of the President of the United States.”

OSHA does not currently require or mandate JSAs across all industries, it does however require JSAs or similar analysis for inclusion in its Voluntary Protection Program (VPP).

## **SAMPLE JSA**

Step	Hazard	Control
(1) Prepare Surface Using Electric Wire Brush	Hand Arm Vibration Syndrome	Wear thick gloves  Use vibrating tool no more than 20 minutes at a time and for no more than 2 hours a shift
	Paint dust possibly containing lead	Wear a P3 organic vapor mask when disturbing old paint. Wear disposable coveralls. Wash hands thoroughly before eating or smoking. Thorough housekeeping.
	Slips trips and falls	Route all electrical cables sensibly to keep walkways and stairs free of hazards.
	Sunburn	Wear broad brim and SPF 40+ sun block.
(2) Paint Handrails	Damage to adjacent surfaces from thinners and paint	Use drop sheets
	Exposure to fumes from thinners	If poorly ventilated, use P3 organic vapor mask
	Paint in eyes	Wear safety goggles when working above shoulder height, safety glasses at other times
	Fire	Keep containers of thinners and flammable solvents closed properly and stored in a cool place away from sources of sparks; keep appropriate fire extinguisher in work area
(3) Housekeeping	Slip and trip hazards	Remove waste to bin, tools to store, ensure barriers and signs are in place to denote wet paint.

## OTHER CONSIDERATIONS

### Assessing Risk Levels

Some organizations have additional columns for risk level. The level of risk is assessed both before applying the control and after applying the control. Risk (in the sphere of OH&S) is defined as Probability X Consequence. Qualitative Risk Assessment uses a Risk Matrix to assess the level of Risk. A risk simple risk matrix looks like this:

H	M	H	H
M	L	M	H
L	L	L	M
	L	M	H

Consequence is measured on the Y-axis, and Probability is measured on the X-axis. Therefore using a grinder without eye goggles has a high probability of causing an adverse event, and has high consequences (blindness) so it represents a high risk. Using the grinder whilst wearing eye goggles reduces this hazard to low probability and low consequences.

Assessing the level of Residual Risk using a risk matrix is recorded on a JSA like this:

		P	C	R		P	C	RR
(3) Housekeeping	Slip and trip hazards	M	H	M	Remove waste to bin, tools to store, ensure barriers and signs are in place to denote wet paint.	L	L	L

The initial risk IR (before putting controls in place) is Medium, according to the Risk Matrix. The Residual Risk RR, after controlling the hazard (in this case with good housekeeping) is Low. If the Residual Risk is not Low, the work group must devise more or better controls until the RR is resolved to Low.

### Identifying Responsibilities

Another column that is often added to the basic three columns in a JSA form or worksheet is the *Responsible* column. The Responsible column is for the name of the individual who will put the particular control in place. Defining who is responsible for actually putting the controls in place that have been identified on the JSA worksheet ensures that an individual is accountable for doing so.

## **After the JSA worksheet is completed**

After the JSA worksheet is completed, the work group that is about to perform the task should have a toolbox talk, and discuss the hazards and controls, delegate responsibilities, ensure that all equipment and PPE described in the JSA are available, that contingencies such as fire fighting are understood, communication channels and hand signals are agreed etcetera. Then, if everybody in the work group feels that it is safe to proceed with task, work should commence.

If at any time during the task circumstances change, then work should be stopped (sometimes called a "time-out for safety"), and the hazards and controls described in the JSA should be reassessed and additional controls used or alternative methods devised. Again, work should only recommence when every member of the work group feels it is safe to do so.

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.

## **Tips and Tricks**

It is vitally important that workers understand that it is not the JSA form that will keep them safe on the job, but rather the process it represents. It is of little value to identify hazards and devise controls if the controls are not put in place.

Workers should never be tempted to "sign on" the bottom of a JSA without first reading and understanding it. JSAs are quasi-legal documents, and are often used in incident investigations, contractual disputes, and court cases.

Everybody in the workforce should be involved in creating the JSA. The more minds, the more years of experience applied to analysing the hazards in a job, the more successful the work group will be in controlling them.

## Chapter 7

# Hazard Prevention & Control Banding

## Hazard Prevention

**Hazard prevention** refers to the **prevention** of risks. The first and most effective stage of hazard prevention and emergency management is the elimination of hazards. If this is too timely or impractical, comes the more costly stage in emergency management: disaster mitigation.

### ***Accident Chain***

Every accident as a result of a hazard is preventable by breaking the accident chain before the last link. Breaking the chain is known as intervention, which is *reactive*, whereas reducing the potential for an accident chain at all is mitigation, which is *proactive*. An example of a reactive step is the creation of a collapse zone at a structure fire. An example of a proactive step is wearing personal protective equipment at a fire call.

The accident chain:

- The environment *such as weather or lighting*
- Human factors *such as training or attitude*
- Equipment *such as proper use and maintenance*
- Event *the unsafe junction of the previous three links*
- Accident *the actual injury or property damage*

## ***Safety Standards and Regulations***

The United States Congress passed the William Steiger Act in 1970 with the signature of Richard Nixon. This established the Occupational Safety and Health Administration (OSHA). OSHA enforces safety-related regulations, known as Codes of Federal Regulation (CFRs) in the workplace.

## **Control Banding**

**Control banding** is a qualitative or semi-quantitative risk assessment and management approach to promoting occupational health and safety. It is intended to minimize worker exposures to hazardous chemicals and other risk factors in the workplace and to help small businesses by providing an easy-to-understand, practical approach to controlling hazardous exposures at work.

The principle of control banding was first applied to dangerous chemicals, chemical mixtures, and fumes. The control banding process emphasizes the controls needed to prevent hazardous substances from causing harm to people at work. The greater the potential for harm, the greater the degree of control needed to manage the situation and make the risk “acceptable.”

A single *control* technology or strategy is matched with a single *band*, or range of exposures (e.g. 1-10 milligrams per cubic meter) for a particular class of chemicals (e.g. skin irritants, reproductive hazards).

Here is an example of four control bands developed for inhalation hazards.

<b>Band no.</b>	<b>Hazard Group</b>	<b>Exposure Concentration</b>	<b>Control Strategy</b>
1	Skin and eye irritants	<1–10 mg/m <sup>3</sup> dust, or >50 to 500 ppm vapor	General ventilation and good industrial hygiene practices.
2	Harmful on single exposure	>0.1 to 1 mg/m <sup>3</sup> dust or >5 to 550 ppm vapor	Local exhaust ventilation
3	Severely irritating and corrosive	>0.01 to 0.1 mg/m <sup>3</sup> dust or <0.5 to 5 ppm vapor	Process enclosure, an engineering control
4	Very toxic on single exposure, reproductive hazard, sensitizer	<0.01 mg/m <sup>3</sup> dust or <0.5 ppm vapor	Seek expert advice

In the United Kingdom, the Health and Safety Executive (HSE) has developed a comprehensive control banding model called *COSHH Essentials* (COSHH stands for *control of substances hazardous to health.*)

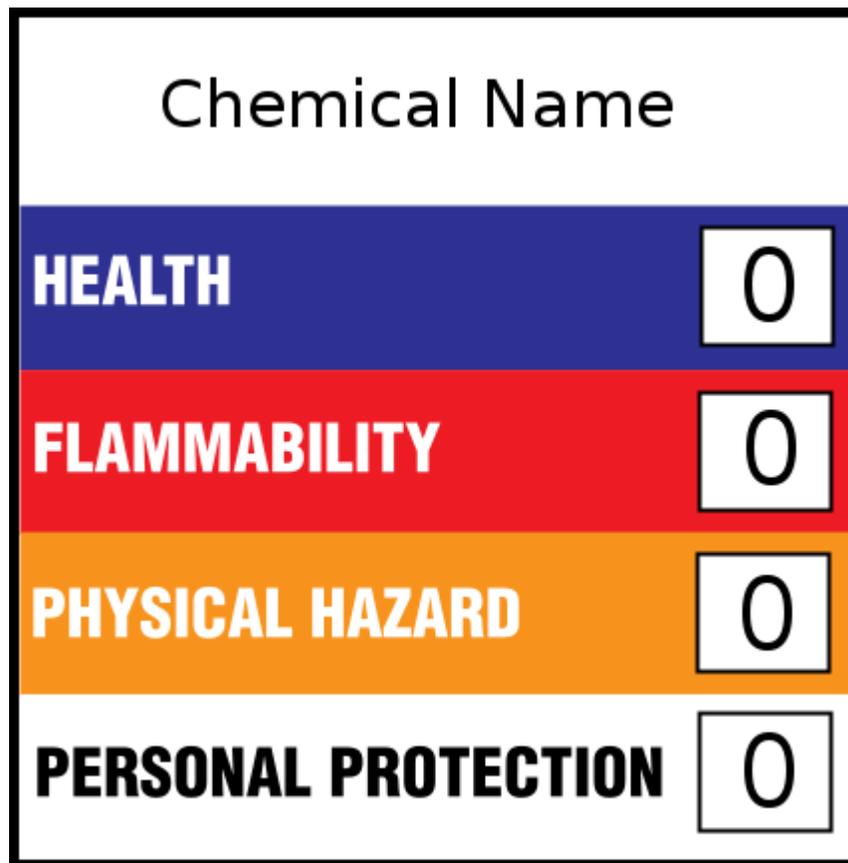
The use of control banding strategies has become very popular in the pharmaceutical industry where early stage development compounds may have little or no toxicology data.

### ***Limitations of Control Banding***

Control banding is not without limitations and still requires professional knowledge and experience to verify that the control measures specified have been properly installed, maintained, and used. Controls should be validated prior to use by either using substance specific industrial hygiene methods or performing surrogate monitoring.

## Chapter 8

# Hazardous Materials Identification System



A sample HMIS Color Bar

**HMIS** (Hazardous Materials Identification System) is a numerical hazard rating that incorporates the use of labels with color-coded bars as well as training materials. It was developed by the National Paint & Coatings Association (NPCA) as a compliance aid for the OSHA Hazard Communication Standard.

## **HMIS Color Bar**

The HMIS Color Bar is similar to the fire diamond, created by the National Fire Protection Association. Before 2002 the fire diamond and the color bar both had sections colored blue, red, white, and yellow. After April 2002, with the release of HMIS III, yellow in the color bar (which stood for reactivity) was replaced by orange, standing for physical hazard. The fire diamond is designed for emergencies when information about the effects of short, or acute, exposure is needed. The color bar is not for emergencies and is used to convey broader health warning information.

## **Symbols**

The four bars are color coded, using the modern color bar symbols with blue indicating the level of health hazard, red for flammability, orange for a physical hazard, and white for Personal Protection. The number ratings range from 0-4.

### **Blue/Health**

The Health section conveys the health hazards of the material. In the latest version of HMIS, the blue Health bar has two spaces, one for an asterisk and one for a numeric hazard rating. If present, the asterisk signifies a chronic health hazard, meaning that long-term exposure to the material could cause a health problem such as emphysema or kidney damage. According to NPCA, the numeric hazard assessment procedure differs from that used by NFPA.

- **4.** Life-threatening, major or permanent damage may result from single or repeated overexposures (eg., hydrogen cyanide).
- **3.** Major injury likely unless prompt action is taken and medical treatment is given.
- **2.** Temporary or minor injury may occur.
- **1.** Irritation or minor reversible injury possible.
- **0.** No significant risk to health.

### **Red/Flammability**

For HMIS I and II, the criteria used to assign numeric values (0 = low hazard to 4 = high hazard) are identical to those used by NFPA. In other words, in this category, the systems are identical. For HMIS III, the flammability criteria are defined according to OSHA standards.

- **4.** Flammable gases, or very volatile flammable liquids with flash points below 73 °F (23 °C), and boiling points below 100 °F (38 °C). Materials may ignite spontaneously with air (eg., Propane).
- **3.** Materials capable of ignition under almost all normal temperature conditions. Includes flammable liquids with flash points below 73 °F (23 °C) and boiling

- points above 100 °F (38 °C), as well as liquids with flash points between 73 °F and 100 °F.
- **2.** Materials which must be moderately heated or exposed to high ambient temperatures before ignition will occur. Includes liquids having a flash point at or above 100 °F (38 °C) but below 200 °F (93 °C) (eg., Diesel fuel).
  - **1.** Materials that must be preheated before ignition will occur. Includes liquids, solids and semi solids having a flash point above 200 °F (eg., Canola oil).
  - **0.** Materials that will not burn (eg., Water).

## **Yellow/Physical Hazard**

Reactivity hazard are assessed using the OSHA criterion of physical hazard. Seven such hazard classes are recognized: Water Reactives, Organic Peroxides, Explosives, Compressed gases, Pyrophoric materials, Oxidizers, and Unstable Reactives.

- **4.** Materials that are readily capable of explosive water reaction, detonation or explosive decomposition, polymerization, or self-reaction at normal temperature and pressure
- **3.** Materials that may form explosive mixtures with water and are capable of detonation or explosive reaction in the presence of a strong initiating source. Materials may polymerize, decompose, self-react, or undergo other chemical change at normal temperature and pressure with moderate risk of explosion.
- **2.** Materials that are unstable and may undergo violent chemical changes at normal temperature and pressure with low risk for explosion. Materials may react violently with water or form peroxides upon exposure to air.
- **1.** Materials that are normally stable but can become unstable (self-react) at high temperatures and pressures. Materials may react non-violently with water or undergo hazardous polymerization in the absence of inhibitors.
- **0.** Materials that are normally stable, even under fire conditions, and will not react with water, polymerize, decompose , condense, or self-react. Non-explosives.

## **White/Personal Protection**

This is by far the largest area of difference between the NFPA and HMIS systems. In the NFPA system, the white area is used to convey special hazards whereas HMIS uses the white section to indicate what personal protective equipment (PPE) should be used when working with the material.

## Chapter 9

# Occupational Safety and Health

**Occupational health and safety** is a cross-disciplinary area concerned with protecting the safety, health and welfare of people engaged in work or employment. The goal of all occupational health and safety programs is to foster a safe work environment. As a secondary effect, it may also protect co-workers, family members, employers, customers, suppliers, nearby communities, and other members of the public who are impacted by the workplace environment. It may involve interactions among many subject areas, including occupational medicine, occupational (or industrial) hygiene, public health, safety engineering, chemistry, health physics.

### ***Definition***

Since 1950, the International Labour Organization (ILO) and the World Health Organization (WHO) have shared a common definition of occupational health. It was adopted by the Joint ILO/WHO Committee on Occupational Health at its first session in 1950 and revised at its twelfth session in 1995. The definition reads: "Occupational health should aim at: the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations; the prevention amongst workers of departures from health caused by their working conditions; the protection of workers in their employment from risks resulting from factors adverse to health; the placing and maintenance of the worker in an occupational environment adapted to his physiological and psychological capabilities; and, to summarize, the adaptation of work to man and of each man to his job". This standard is based on the methodology known as ***Plan-Do-Check-Act (PDCA)***

### ***Relationship to occupational health psychology***

Occupational health psychology (OHP), a related discipline, is a relatively new field that combines elements of occupational health and safety, industrial/organizational psychology, and health psychology. The field is concerned with identifying work-related

psychosocial factors that adversely affect the health of people who work. OHP is also concerned with developing ways to effect change in workplaces for the purpose of improving the health of people who work.

## ***Reasons for Occupational health and safety***

The event of an incident at work (such as legal fees, fines, compensatory damages, investigation time, lost production, lost goodwill from the workforce, from customers and from the wider community).

- Legal - Occupational requirements may be reinforced in civil law and/or criminal law; it is accepted that without the extra "encouragement" of potential regulatory action or litigation, many organizations would not act upon their implied moral obligations.

Occupational health and safety officers promote health and safety procedures in an organisation. They recognize hazards and measure health and safety risks, set suitable safety controls in place, and give recommendations on avoiding accidents to management and employees in an organisation. This paper looks at the main tasks undertaken by OHS practitioners in Europe, Australia and the USA, and the main knowledge and skills that are required of them. "Like it or not, organisations have a duty to provide health and safety training. But it could involve much more than you think." (Damon, Nadia. 2008. 'Reducing The Risks', Training and Coaching Today, United Kingdom, pg.14)

An effective training program can reduce the number of injuries and deaths, property damage, legal liability, illnesses, workers' compensation claims, and missed time from work. A safety training program can also help a trainer keep the required OSHA-mandated safety training courses organized and up-to-date.

Safety training classes help establish a safety culture in which employees themselves help promote proper safety procedures while on the job. It is important that new employees be properly trained and embrace the importance of workplace safety as it is easy for seasoned workers to negatively influence the new hires. That negative influence however, can be purged with the establishment of new, hands-on, innovative effective safety training which will ultimately lead to an effective safety culture. A 1998 NIOSH study concluded that the role of training in developing and maintaining effective hazard control activities is a proven and successful method of intervention.

## **Safety Professionals in Europe**

In Norway, the main required tasks of an Occupational Health and Safety Practitioner include:

- Systematic evaluations of the working environment
- Endorsing preventative measures which eliminate reasons for illnesses in the work place

- Giving information in the subject of employees' health
- Giving information on occupational hygiene, ergonomics and also environmental and safety risks in the work place (Hale A, Ytehus I, 2004, 'Changing requirements for the safety profession: roles and tasks', Journal of Occupational Health & Safety – Australia and New Zealand)

In the Netherlands, required tasks for health and safety staff are only summarily defined, and include:

- Voluntary medical examinations
- A consulting room on the work environment for the workers
- Health check assessments (if needed for the job concerned) (Hale, A et alia. 2004)

'The main influence on the Dutch law on the job of the safety professional is through the requirement on each employer to use the services of a certified working conditions service to advise them on health and safety' (Hale, A et alia. 2004). A 'certified service' must employ sufficient numbers of four types of certified experts to cover the risks in the organisations which use the service:

- A safety professional
- An occupational hygienist
- An occupational physician
- A work and organisation specialist. (Hale, A et alia. 2004)

It shows in Table 1 (based on the European Network of Safety and Health Practitioner Organisations [ENHSPO] survey to) that in Norway, 37 % of Health and Safety practitioners had a MSc education level, and 14% in the Netherlands; 44% were BSc graduates and 63% in the Netherlands; and 19% were of a Technician level and 23% in the Netherlands (Hale, A et alia. 2004).

## **Safety Professionals in the USA**

The main tasks undertaken by the OHS practitioner in the USA include:

- Develop processes, procedures, criteria, requirements, and methods to attain the best possible management of the hazards and exposures that can cause injury to people, and damage property, or the environment;
- Apply good business practices and economic principles for efficient use of resources to add to the importance of the safety processes;
- Promote other members of the company to contribute by exchanging ideas and other different approaches to make sure that every one in the corporation possess OHS knowledge and have functional roles in the development and execution of safety procedures;

- Assess services, outcomes, methods, equipment, workstations, and procedures by using qualitative and quantitative methods to recognise the hazards and measure the related risks;
- Examine all possibilities, effectiveness, reliability, and expenditure to attain the best results for the company concerned

Knowledge required by the OHS professional in USA include:

- Constitutional and case law controlling safety, health, and the environment
- Operational procedures to plan/ develop safe work practices
- Safety, health and environmental sciences
- Design of hazard control systems (i.e. fall protection, scaffoldings)
- Design of recordkeeping systems that take collection into account, as well as storage, interpretation, and dissemination
- Mathematics and statistics
- Processes and systems for attaining safety through design

(Board of Certified Safety Professionals, 2006)

Some skills required by the OHS professional in the USA include (but are not limited to):

- Understanding and relating to systems, policies and rules
- Holding checks and having control methods for possible hazardous exposures
- Mathematical and statistical analysis
- Examining manufacturing hazards
- Planning safe work practices for systems, facilities, and equipment
- Understanding and using safety, health, and environmental science information for the improvement of procedures
- Interpersonal communication skills

(Board of Certified Safety Professionals, 2006)

## ***The differences in each location***

Similar to the findings of the ENHSPO survey conducted in Australia, the Institute of Occupational Medicine found that in the UK, there is a need to put a greater emphasis on work-related illness (Anonymous. 2008. 'Occupational Health', Health and Safety News: In Brief, Vol 60, Iss. 3; UK. pg. 6). It has been shown that in Australia and the USA that a major responsibility of the OHS professional is to keep company directors and managers aware of the issues that they face in regards to Occupational Health and Safety principles and legislation. However, in Europe, it has been shown that this is where they are lacking. "Nearly half of senior managers and company directors do not have an up-to-date understanding of their health and safety-related duties and responsibilities." (Paton, Nic. 2008. 'Senior Managers Fail to Show Competence in Health and Safety' Occupational Health, Vol. 60, Iss. 3; pg. 6)

## ***National implementing legislation***

Different states take different approaches to legislation, regulation, and enforcement.

In the European Union, member states have enforcing authorities to ensure that the basic legal requirements relating to occupational health and safety are met. In many EU countries, there is strong cooperation between employer and worker organisations (e.g. Unions) to ensure good OSH performance as it is recognized this has benefits for both the worker (through maintenance of health) and the enterprise (through improved productivity and quality). In 1996 the European Agency for Safety and Health at Work was founded.

Member states of the European Union have all transposed into their national legislation a series of directives that establish minimum standards on occupational health and safety. These directives (of which there are about 20 on a variety of topics) follow a similar structure requiring the employer to assess the workplace risks and put in place preventive measures based on a hierarchy of control. This hierarchy starts with elimination of the hazard and ends with personal protective equipment.

In the UK, health and safety legislation is drawn up and enforced by the Health and Safety Executive and local authorities (the local council) under the Health and Safety at Work etc. Act 1974. Increasingly in the UK the regulatory trend is away from prescriptive rules, and towards risk assessment. Recent major changes to the laws governing asbestos and fire safety management embrace the concept of risk assessment.

In the United States, the Occupational Safety and Health Act of 1970 created both the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA). OSHA, in the U.S. Department of Labor, is responsible for developing and enforcing workplace safety and health regulations. NIOSH, in the U.S. Department of Health and Human Services, is focused on research, information, education, and training in occupational safety and health.

OSHA have been regulating occupational safety and health since 1971. Occupational safety and health regulation of a limited number of specifically defined industries was in place for several decades before that, and broad regulations by some individual states was in place for many years prior to the establishment of OSHA.

In Canada, workers are covered by provincial or federal labour codes depending on the sector in which they work. Workers covered by federal legislation (including those in mining, transportation, and federal employment) are covered by the Canada Labour Code; all other workers are covered by the health and safety legislation of the province they work in. The Canadian Centre for Occupational Health and Safety (CCOHS), an agency of the Government of Canada, was created in 1978 by an Act of Parliament. The act was based on the belief that all Canadians had "...a fundamental right to a healthy and safe working environment." CCOHS is mandated to promote safe and healthy workplaces to help prevent work-related injuries and illnesses.

In Malaysia, the Department of Occupational Safety and Health (DOSH) under the Ministry of Human Resource is responsible to ensure that the safety, health and welfare of workers in both the public and private sector is upheld. DOSH is responsible to enforce the Factory and Machinery Act 1969 and the Occupational Safety and Health Act 1994.

In the People's Republic of China, the Ministry of Health is responsible for occupational disease prevention and the State Administration of Work Safety for safety issues at work. On the provincial and municipal level, there are Health Supervisions for occupational health and local bureaus of Work Safety for safety. The "Occupational Disease Control Act of PRC" came into force on May 1, 2002. and Work safety Act of PRC on November 1, 2002. The Occupational Disease Control Act is under revising. The prevention of occupational disease is still in its initial stage compared with industrialized countries such as the US or UK.

## ***Identifying Safety and Health Hazards***

### **Hazards, risks, outcomes**

The terminology used in OSH varies between states, but generally speaking:

- A hazard is something that can cause harm if not controlled.
- The outcome is the harm that results from an uncontrolled hazard.
- A risk is a combination of the probability that a particular outcome will occur and the severity of the harm involved.

“Hazard”, “risk”, and “outcome” are used in other fields to describe e.g. environmental damage, or damage to equipment. However, in the context of OSH, “harm” generally describes the direct or indirect degradation, temporary or permanent, of the physical, mental, or social well-being of workers. For example, repetitively carrying out manual handling of heavy objects is a hazard. The outcome could be a musculoskeletal disorder

(MSD) or an acute back or joint injury. The risk can be expressed numerically (e.g. a 0.5 or 50/50 chance of the outcome occurring during a year), in relative terms (e.g. "high/medium/low"), or with a multi-dimensional classification scheme (e.g. situation-specific risks).

## **Hazard Assessment**

Hazard analysis or hazard assessment is a process in which individual hazards of the workplace are identified, assessed and controlled/eliminated as close to source (location of the hazard) as reasonable and possible. As technology, resources, social expectation or regulatory requirements change, hazard analysis focuses controls more closely toward the source of the hazard. Thus hazard control is a dynamic program of prevention. Hazard-based programs also have the advantage of not assigning or implying there are "acceptable risks" in the workplace. A hazard-based program may not be able to eliminate all risks, but neither does it accept "satisfactory" -- but still risky—outcomes. And as those who calculate and manage the risk are usually managers while those exposed to the risks are a different group, workers, a hazard-based approach can by-pass conflict inherent in a risk-based approach.

## **Risk assessment**

Modern occupational safety and health legislation usually demands that a risk assessment be carried out prior to making an intervention. It should be kept in mind that risk management requires risk to be managed to a level which is as low as is reasonably practical.

### **This assessment should:**

- Identify the hazards
- Identify all affected by the hazard and how
- Evaluate the risk
- Identify and prioritize appropriate control measures

The calculation of risk is based on the likelihood or probability of the harm being realized and the severity of the consequences. This can be expressed mathematically as a quantitative assessment (by assigning low, medium and high likelihood and severity with integers and multiplying them to obtain a risk factor, or qualitatively as a description of the circumstances by which the harm could arise.

The assessment should be recorded and reviewed periodically and whenever there is a significant change to work practices. The assessment should include practical recommendations to control the risk. Once recommended controls are implemented, the risk should be re-calculated to determine if it has been lowered to an acceptable level. Generally speaking, newly introduced controls should lower risk by one level, i.e., from high to medium or from medium to low.

## Common workplace hazard groups

- **Mechanical hazards** include:

*By type of agent:*

- - Impact force
    - Collisions
    - Falls from height
  - Struck by objects
  - Confined space
  - Slips and trips
  - Falling on a pointed object
  - Compressed air/high pressure fluids (such as cutting fluid)
  - Entanglement
  - Equipment-related injury

*By type of damage:*

- - Crushing
  - Cutting
  - Friction and abrasion
  - Shearing
  - Stabbing and puncture
- **Other physical hazards:**
  - Noise
  - Vibration
  - Lighting
  - Barotrauma (hypobaric/hyperbaric pressure)
  - Ionizing radiation
  - Electricity
  - Asphyxiation
  - Cold stress (hypothermia)
  - Heat stress (hyperthermia)
    - Dehydration (due to sweating)
- **Biological hazards** include:
  - Bacteria
  - Virus
  - Fungi
    - Mold
  - Blood-borne pathogens



Harry McShane, age 16, 1908. Pulled into machinery in a factory in Cincinnati. His arm was ripped off at the shoulder and his leg broken. No compensation paid. Photograph by Lewis Hine.

- **Chemical hazards** include:
  - Acids
  - Bases
  - Heavy metals
    - Lead
  - Solvents
    - Petroleum
  - Particulates
    - Asbestos and other fine dust/fibrous materials
    - Silica
  - Fumes (noxious gases/vapors)
  - Highly-reactive chemicals
  - Fire, conflagration and explosion hazards:
    - Explosion
    - Deflagration
    - Detonation
    - Conflagration
- **Psychosocial issues** include:
  - Work-related stress, whose causal factors include excessive working time and overwork

- Tuberculosis
  - Violence from outside the organisation
  - Bullying, which may include emotional and verbal abuse
  - Sexual harassment
  - Mobbing
  - Burnout
  - Exposure to unhealthy elements during meetings with business associates, e.g. tobacco, uncontrolled alcohol
- **Musculoskeletal disorders**, avoided by the employment of good ergonomic design

Fire prevention (fire protection/fire safety) often comes within the remit of health and safety professionals as well.

### **Canadian Classification**

In Canada, Hazards are typically categorized into one of six groups:

1. Safety (moving machinery, working at heights, slippery surfaces, mobile equipment, etc.)
2. Ergonomic (material handling, environment, work organization, etc.)
3. Chemical Agents
4. Biological Agents
5. Physical Agents(noise, lighting, radiation, etc.)
6. Psychosocial(stress, violence, etc.)

## ***Future developments***

Occupational health and safety has come a long way from its beginnings in the heavy industry sector. It now has an impact on every worker, in every work place, and those charged with managing health and safety are having more and more tasks added to their portfolio. The most significant responsibility is environmental protection. The skills required to manage occupational health and safety are compatible with environmental protection, which is why these responsibilities are so often bolted onto the workplace health and safety professional.

## Chapter 10

# Safety Engineering

**Safety engineering** is an applied science strongly related to systems engineering and the subset System Safety Engineering. Safety engineering assures that a life-critical system behaves as needed even when pieces fail.

### **Overview**

Ideally, safety-engineers take an early design of a system, analyze it to find what faults can occur, and then propose safety requirements in design specifications up front and changes to existing systems to make the system safer. In an early design stage, often a fail-safe system can be made acceptably safe with a few sensors and some software to read them. Probabilistic fault-tolerant systems can often be made by using more, but smaller and less-expensive pieces of equipment.

Far too often, rather than actually influencing the design, safety engineers are assigned to prove that an existing, completed design is safe. If a safety engineer then discovers significant safety problems late in the design process, correcting them can be very expensive. This type of error has the potential to waste large sums of money.

The exception to this conventional approach is the way some large government agencies approach safety engineering from a more proactive and proven process perspective, known as "system safety". The system safety philosophy is to be applied to complex and critical systems, such as commercial airliners, complex weapon systems, spacecraft, rail and transportation systems, air traffic control system and other complex and safety-critical industrial systems. The proven system safety methods and techniques are to prevent, eliminate and control hazards and risks through designed influences by a collaboration of key engineering disciplines and product teams. Software safety is a fast growing field since modern systems functionality are increasingly being put under control of software. The whole concept of system safety and software safety, as a subset of systems engineering, is to influence safety-critical systems designs by conducting

several types of hazard analyses to identify risks and to specify design safety features and procedures to strategically mitigate risk to acceptable levels before the system is certified.

Additionally, failure mitigation can go beyond design recommendations, particularly in the area of maintenance. There is an entire realm of safety and reliability engineering known as Reliability Centered Maintenance (RCM), which is a discipline that is a direct result of analyzing potential failures within a system and determining maintenance actions that can mitigate the risk of failure. This methodology is used extensively on aircraft and involves understanding the failure modes of the serviceable replaceable assemblies in addition to the means to detect or predict an impending failure. Every automobile owner is familiar with this concept when they take in their car to have the oil changed or brakes checked. Even filling up one's car with fuel is a simple example of a failure mode (failure due to fuel exhaustion), a means of detection (fuel gauge), and a maintenance action (filling the car's fuel tank).

For large scale complex systems, hundreds if not thousands of maintenance actions can result from the failure analysis. These maintenance actions are based on conditions (e.g., gauge reading or leaky valve), hard conditions (e.g., a component is known to fail after 100 hrs of operation with 95% certainty), or require inspection to determine the maintenance action (e.g., metal fatigue). The RCM concept then analyzes each individual maintenance item for its risk contribution to safety, mission, operational readiness, or cost to repair if a failure does occur. Then the sum total of all the maintenance actions are bundled into maintenance intervals so that maintenance is not occurring around the clock, but rather, at regular intervals. This bundling process introduces further complexity, as it might stretch some maintenance cycles, thereby increasing risk, but reduce others, thereby potentially reducing risk, with the end result being a comprehensive maintenance schedule, purpose built to reduce operational risk and ensure acceptable levels of operational readiness and availability.

## ***Analysis techniques***

Analysis techniques can be split into two categories: qualitative and quantitative methods. The both approaches share the goal of finding causal dependencies between an hazard on system level and failures of individual components. Qualitative approaches focus on the question "What must go wrong, such that a system hazard may occur?", while quantitative methods aim at providing estimations about probabilities, rates and/or severity of consequences.

Traditionally, safety analysis techniques rely solely on skill and expertise of the safety engineer. In the last decade model-based approaches have become prominent. In contrast to traditional methods, model-based techniques try to derive relationships between causes and consequences from some sort of model of the system.

## **Traditional methods for safety analysis**

The two most common fault modeling techniques are called failure mode and effects analysis and fault tree analysis. These techniques are just ways of finding problems and of making plans to cope with failures, as in probabilistic risk assessment. One of the earliest complete studies using this technique on a commercial nuclear plant was the WASH-1400 study, also known as the Reactor Safety Study or the Rasmussen Report.

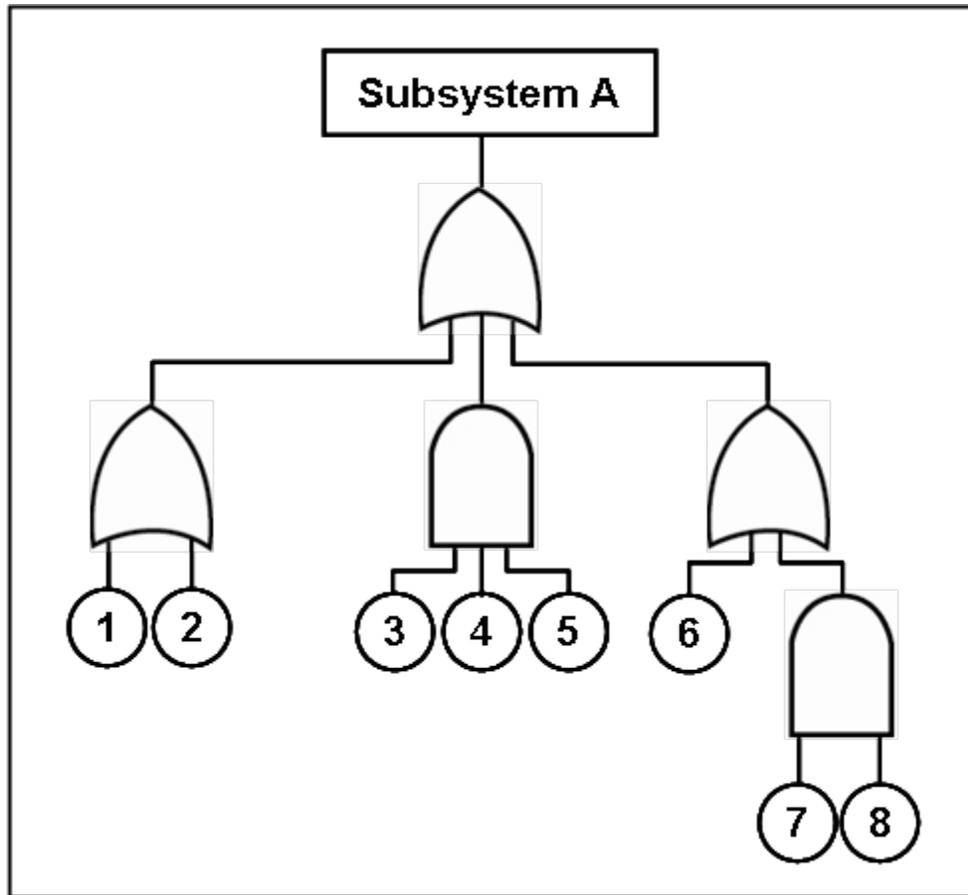
### **Failure modes and effects analysis**

Failure Mode and Effects Analysis (FMEA) is a bottom-up, inductive analytical method which may be performed at either the functional or piece-part level. For functional FMEA, failure modes are identified for each function in a system or equipment item, usually with the help of a functional block diagram. For piece-part FMEA, failure modes are identified for each piece-part component (such as a valve, connector, resistor, or diode). The effects of the failure mode are described, and assigned a probability based on the failure rate and failure mode ratio of the function or component.

Failure modes with identical effects can be combined and summarized in a Failure Mode Effects Summary. When combined with criticality analysis, FMEA is known as Failure Mode, Effects, and Criticality Analysis or FMECA, pronounced "fuh-MEE-kuh".

### **Fault tree analysis**

Fault tree analysis (FTA) is a top-down, deductive analytical method. In FTA, initiating primary events such as component failures, human errors, and external events are traced through Boolean logic gates to an undesired top event such as an aircraft crash or nuclear reactor core melt. The intent is to identify ways to make top events less probable, and verify that safety goals have been achieved.



A fault tree diagram

Fault trees are a logical inverse of success trees, and may be obtained by applying de Morgan's theorem to success trees (which are directly related to reliability block diagrams).

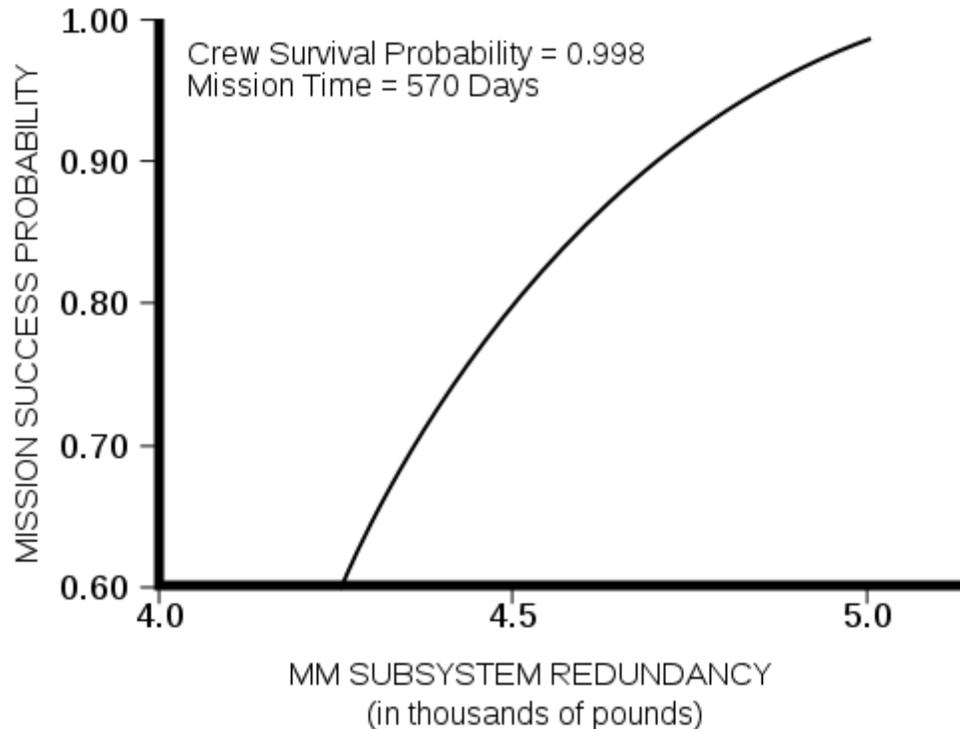
FTA may be qualitative or quantitative. When failure and event probabilities are unknown, qualitative fault trees may be analyzed for minimal cut sets. For example, if any minimal cut set contains a single base event, then the top event may be caused by a single failure. Quantitative FTA is used to compute top event probability, and usually requires computer software such as CAFTA from the Electric Power Research Institute or SAPHIRE from the Idaho National Laboratory.

Some industries use both fault trees and event trees. An event tree starts from an undesired initiator (loss of critical supply, component failure etc.) and follows possible further system events through to a series of final consequences. As each new event is considered, a new node on the tree is added with a split of probabilities of taking either branch. The probabilities of a range of "top events" arising from the initial event can then be seen.

## ***Safety certification***

Usually a failure in safety-certified systems is acceptable if, on average, less than one life per  $10^9$  hours of continuous operation is lost to failure. Most Western nuclear reactors, medical equipment, and commercial aircraft are certified to this level. The cost versus loss of lives has been considered appropriate at this level (by FAA for aircraft under Federal Aviation Regulations).

## ***Preventing failure***



A NASA graph shows the relationship between the survival of a crew of astronauts and the amount of redundant equipment in their spacecraft (the "MM", Mission Module).

## **Probabilistic fault tolerance: adding redundancy to equipment and systems**

Once a failure mode is identified, it can usually be prevented entirely by adding extra equipment to the system. For example, nuclear reactors contain dangerous radiation, and nuclear reactions can cause so much heat that no substance might contain them.

Therefore reactors have emergency core cooling systems to keep the temperature down, shielding to contain the radiation, and engineered barriers (usually several, nested, surmounted by a containment building) to prevent accidental leakage.

Most biological organisms have a certain amount of redundancy: multiple organs, multiple limbs, etc.

For any given failure, a fail-over or redundancy can almost always be designed and incorporated into a system.

## ***When does safety stop, where does reliability begin?***

### **Inherent fail-safe design**

When adding equipment is impractical (usually because of expense), then the least expensive form of design is often "inherently fail-safe". The typical approach is to arrange the system so that ordinary single failures cause the mechanism to shut down in a safe way (for nuclear power plants, this is termed a passively safe design, although more than ordinary failures are covered).

One of the most common fail-safe systems is the overflow tube in baths and kitchen sinks. If the valve sticks open, rather than causing an overflow and damage, the tank spills into an overflow.

Another common example is that in an elevator the cable supporting the car keeps spring-loaded brakes open. If the cable breaks, the brakes grab rails, and the elevator cabin does not fall.

Inherent fail-safes are common in medical equipment, traffic and railway signals, communications equipment, and safety equipment.

### ***Containing failure***

It is also common practice to plan for the failure of safety systems through containment and isolation methods. The use of isolating valves, also known as the block and bleed manifold, is very common in isolating pumps, tanks, and control valves that may fail or need routine maintenance. In addition, nearly all tanks containing oil or other hazardous chemicals are required to have containment barriers set up around them to contain 100% of the volume of the tank in the event of a catastrophic tank failure. Similarly, in a long pipeline, there are remote-closing valves at regular intervals so that a leak can be isolated. The goal of all containment systems is to provide means of mitigating the consequences of failure.

## Chapter 11

# Failure Mode, Effects, and Criticality Analysis

**Failure mode, effects, and criticality analysis (FMECA)** is an extension of failure mode and effects analysis (FMEA). FMEA is a bottom-up, inductive analytical method which may be performed at either the functional or piece-part level. FMECA extends FMEA by including a *criticality analysis*, which is used to chart the probability of failure modes against the severity of their consequences. The result highlights failure modes with relatively high probability and severity of consequences, allowing remedial effort to be directed where it will produce the greatest value. FMECA tends to be preferred over FMEA in space and North Atlantic Treaty Organization (NATO) military applications, while various forms of FMEA predominate in other industries.

### **History**

FMECA was originally developed in the 1940s by the U.S military, which published MIL-P-1629 in 1949. By the early 1960s, contractors for the U.S. National Aeronautics and Space Administration (NASA) were using variations of FMECA under a variety of names. In 1966 NASA released its FMECA procedure for use on the Apollo program. FMECA was subsequently used on other NASA programs including Viking, Voyager, Magellan, and Galileo. Possibly because MIL-P-1629 was replaced by MIL-STD-1629 (SHIPS) in 1974, development of FMECA is sometimes incorrectly attributed to NASA. At the same time as the space program developments, use of FMEA and FMECA was already spreading to civil aviation. In 1967 the Society for Automotive Engineers released the first civil publication to address FMECA. The civil aviation industry now tends to use a combination of FMEA and Fault Tree Analysis in accordance with SAE ARP4761 instead of FMECA, though some helicopter manufacturers continue to use FMECA for civil rotorcraft.

Ford Motor Company began using FMEA in the 1970s after problems experienced with its Pinto model, and by the 1980s FMEA was gaining broad use in the automotive industry. In Europe, the International Electrotechnical Commission published IEC 812

(now IEC 60812) in 1985, addressing both FMEA and FMECA for general use. The British Standards Institute published BS 5760-5 in 1991 for the same purpose.

In 1980, MIL-STD-1629A replaced both MIL-STD-1629 and the 1977 aeronautical FMECA standard MIL-STD-2070. MIL-STD-1629A was canceled without replacement in 1998, but nonetheless remains in wide use for military and space applications today.

## **Methodology**

Slight differences are found between the various FMECA standards. By RAC CRTA-FMECA, the FMECA analysis procedure typically consists of the following logical steps:

- Define the system
- Define ground rules and assumptions in order to help drive the design
- Construct system block diagrams
- Identify failure modes (piece part level or functional)
- Analyze failure effects/causes
- Feed results back into design process
- Classify the failure effects by severity
- Perform criticality calculations
- Rank failure mode criticality
- Determine critical items
- Feed results back into design process
- Identify the means of failure detection, isolation and compensation
- Perform maintainability analysis
- Document the analysis, summarize uncorrectable design areas, identify special controls necessary to reduce failure risk
- Make recommendations
- Follow up on corrective action implementation/effectiveness

FMECA may be performed at the functional or piece part level. Functional FMECA considers the effects of failure at the functional block level, such as a power supply or an amplifier. Piece part FMECA considers the effects of individual component failures, such as resistors, transistors, microcircuits, or valves. A piece part FMECA requires far more effort, but is sometimes preferred because it relies more on quantitative data and less an engineering judgment than a functional FMECA.

The criticality analysis may be quantitative or qualitative, depending on the availability of supporting part failure data.

## **System definition**

In this step, the major system to be analyzed is defined and partitioned into an indented hierarchy such as systems, subsystems or equipment, units or subassemblies, and piece parts. Functional descriptions are created for the systems and allocated to the subsystems, covering all operational modes and mission phases.

## **Ground rules and assumptions**

Before detailed analysis takes place, ground rules and assumptions are usually defined and agreed to. This might include, for example:

- Standardized mission profile with specific fixed duration mission phases
- Sources for failure rate and failure mode data
- Fault detection coverage that system built-in test will realize
- Whether the analysis will be functional or piece part
- Criteria to be considered (mission abort, safety, maintenance, etc.)
- System for uniquely identifying parts or functions
- Severity category definitions

## **Block diagrams**

Next, the systems and subsystems are depicted in functional block diagrams. Reliability block diagrams or fault trees are usually constructed at the same time. These diagrams are used to trace information flow at different levels of system hierarchy, identify critical paths and interfaces, and identify the higher level effects of lower level failures.

## **Failure mode identification**

For each piece part or each function covered by the analysis, a complete list of failure modes is developed. For functional FMECA, typical failure modes include:

- Untimely operation
- Failure to operate when required
- Loss of output
- Intermittent output
- Erroneous output (given the current condition)
- Invalid output (for any condition)

For piece part FMECA, failure mode data may be obtained from databases such as RAC FMD-91 or RAC FMD-97. These databases provide not only the failure modes, but also the failure mode ratios. For example:

### Device Failure Modes and Failure Mode Ratios (FMD-91)

Device Type	Failure Mode	Ratio ( $\alpha$ )
Relay	Fails to trip	.55
	Spurious trip	.26
	Short	.19
Resistor, Composition	Parameter change	.66
	Open	.31
	Short	.93

Each function or piece part is then listed in matrix form with one row for each failure mode. Because FMECA usually involves very large data sets, a unique identifier must be assigned to each item (function or piece part), and to each failure mode of each item.

### Failure effects analysis

Failure effects are determined and entered for each row of the FMECA matrix, considering the criteria identified in the ground rules. Effects are separately described for the local, next higher, and end (system) levels. System level effects may include:

- System failure
- Degraded operation
- System status failure
- No immediate effect

The failure effect categories used at various hierarchical levels are tailored by the analyst using engineering judgment.

## Severity classification

Severity classification is assigned for each failure mode of each unique item and entered on the FMECA matrix, based upon system level consequences. A small set of classifications, usually having 3 to 10 severity levels, is used. For example, When prepared using MIL-STD-1629A, failure or mishap severity classification normally follows MIL-STD-882.

### Mishap Severity Categories (MIL-STD-882)

Category	Description	Criteria
I	Catastrophic	Could result in death, permanent total disability, loss exceeding \$1M, or irreversible severe environmental damage that violates law or regulation.
II	Critical	Could result in permanent partial disability, injuries or occupational illness that may result in hospitalization of at least three personnel, loss exceeding \$200K but less than \$1M, or reversible environmental damage causing a violation of law or regulation.
III	Marginal	Could result in injury or occupational illness resulting in one or more lost work days(s), loss exceeding \$10K but less than \$200K, or mitigatable environmental damage without violation of law or regulation where restoration activities can be accomplished.
IV	Negligible	Could result in injury or illness not resulting in a lost work day, loss exceeding \$2K but less than \$10K, or minimal environmental damage not violating law or regulation.

Current FMECA severity categories for U.S. Federal Aviation Administration (FAA), NASA and European Space Agency space applications are derived from MIL-STD-882.

## Failure detection methods

For each component and failure mode, the ability of the system to detect and report the failure in question is analyzed. One of the following will be entered on each row of the FMECA matrix:

- *Normal*: the system correctly indicates a safe condition to the crew
- *Abnormal*: the system correctly indicates a malfunction requiring crew action
- *Incorrect*: the system erroneously indicates a safe condition in the event of malfunction, or alerts the crew to a malfunction that does not exist (false alarm)

## Criticality ranking

Failure mode criticality assessment may be qualitative or quantitative. For qualitative assessment, a mishap probability code or number is assigned and entered on the matrix. For example, MIL–STD–882 uses five probability levels:

### Failure Probability Levels (MIL–STD–882)

Description Level		Individual Item	Fleet
Frequent	A	Likely to occur in the life of the item	Continuously experienced
Probable	B	Will occur several times in the life of an item	Will occur frequently
Occasional	C	Likely to occur some time in the life of an item	Will occur several times
Remote	D	Unlikely but possible to occur in the life of an item	Unlikely, but can reasonably be expected to occur
Improbable	E	So unlikely, it can be assumed occurrence may not be experienced	Unlikely to occur, but possible

The failure mode may then be charted on a criticality matrix using severity code as one axis and probability level code as the other. For quantitative assessment, *modal criticality number*  $C_m$  is calculated for each failure mode of each item, and *item criticality number*  $C_r$  is calculated for each item. The criticality numbers are computed using the following values:

- Basic failure rate  $\lambda_p$
- Failure mode ratio  $\alpha$

- Conditional probability  $\beta$
- Mission phase duration  $t$

$$C_r = \sum_{n=1}^N (C_m)_n$$

The criticality numbers are computed as  $C_m = \lambda_p \alpha \beta t$  and  $C_r = \sum_{n=1}^N (C_m)_n$ . The basic failure rate  $\lambda_p$  is usually fed into the FMECA from a failure rate prediction based on MIL-HDBK-217, PRISM, RIAC 217Plus, or a similar model. The failure mode ratio may be taken from a database source such as RAC FMD-97. For functional level FMECA, engineering judgment may be required to assign failure mode ratio. The conditional probability number  $\beta$  represents the conditional probability that the failure effect will result in the identified severity classification, given that the failure mode occurs. It represents the analyst's best judgment as to the likelihood that the loss will occur. For graphical analysis, a criticality matrix may be charted using either  $C_m$  or  $C_r$  on one axis and severity code on the other.

### **Critical item/failure mode list**

Once the criticality assessment is completed for each failure mode of each item, the FMECA matrix may be sorted by severity and qualitative probability level or quantitative criticality number. This enables the analysis to identify critical items and critical failure modes for which design mitigation is desired.

### **Recommendations**

After performing FMECA, recommendations are made to design to reduce the consequences of critical failures. This may include selecting components with higher reliability, reducing the stress level at which a critical item operates, or adding redundancy or monitoring to the system.

### **Maintainability analysis**

FMECA usually feeds into both Maintainability Analysis and Logistics Support Analysis, which both require data from the FMECA.

### **FMECA report**

A FMECA report consists of system description, ground rules and assumptions, conclusions and recommendations, corrective actions to be tracked, and the attached FMECA matrix which may be in spreadsheet, worksheet, or database form.

### **Risk priority calculation**

RAC CRTA-FMECA and MIL-HDBK-338 both identify Risk Priority Number (RPN) calculation is an alternate method to criticality analysis. The *RPN* is a result of a multiplication of detectability (*D*) x severity (*S*) x occurrence (*O*). Each on a scale from 1

to 10. The highest *RPN* is  $10 \times 10 \times 10 = 1000$ . This means that this failure is not detectable by inspection, very severe and the occurrence is almost sure. If the occurrence is very sparse, this would be 1 and the *RPN* would decrease to 100. So, criticality analysis enables to focus on the highest risks.

### ***Advantages and disadvantages***

Strengths of FMECA include its comprehensiveness, the systematic establishment of relationships between failure causes and effects, and its ability to point out individual failure modes for corrective action in design. Weaknesses include the extensive labor required, the large number of trivial cases considered, and inability to deal with multiple-failure scenarios or unplanned cross-system effects such as sneak circuits.

According to an FAA research report for commercial space transportation,

*Failure Modes, effects, and Criticality Analysis is an excellent hazard analysis and risk assessment tool, but it suffers from other limitations. This alternative does not consider combined failures or typically include software and human interaction considerations. It also usually provides an optimistic estimate of reliability. Therefore, FMECA should be used in conjunction with other analytical tools when developing reliability estimates.*