Concepts & Principles of Cause and Effect Analysis

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QCTO: Occupational Health, Safety Quality Practitioner Qualification – NQF Level 5

ISO NET (Pty) Ltd

Learner Guide

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CAUSES AND EFFECTS OF HAZARD IDENTIFICATION

What is a hazard?

There are many definitions for hazard but the most common definition when talking about workplace health and safety is “A hazard is any source of potential damage, harm or adverse health effects on something or someone.”

The CSA Z1002 Standard "Occupational health and safety - Hazard identification and elimination and risk assessment and control" uses the following terms:

- Harm – physical injury or damage to health.
- Hazard – a potential source of harm to a worker.

Basically, a hazard is the potential for harm or an adverse effect (for example, to people as health effects, to organizations as property or equipment losses, or to the environment).

Please see the OSH Answers on Hazard and Risk for more information

What is hazard identification?

Hazard identification is part of the process used to evaluate if any particular situation, item, thing, etc. may have the potential to cause harm. The term often used to describe the full process is risk assessment:

- Identify hazards and risk factors that have the potential to cause harm (hazard identification).
- Analyze and evaluate the risk associated with that hazard (risk analysis, and risk evaluation).
- Determine appropriate ways to eliminate the hazard, or control the risk when the hazard cannot be eliminated (risk control).

Overall, the goal of hazard identification is to find and record possible hazards that may be present in your workplace. It may help to work as a team and include both people familiar with the work area, as well as people who are not – this way you have both the experienced and fresh eye to conduct the inspection.

When should hazard identification be done?

Hazard identification can be done:

- During design and implementation
  - Designing a new process or procedure
  - Purchasing and installing new machinery
- Before tasks are done
  - Checking equipment or following processes
  - Reviewing surroundings before each shift
- While tasks are being done
  - Be aware of changes, abnormal conditions, or sudden emissions
- During inspections
  - Formal, informal, supervisor, health and safety committee

- After incidents
    - Near misses or minor events
    - Injuries

To be sure that all hazards are found:

- Look at all aspects of the work and include non-routine activities such as maintenance, repair, or cleaning.
- Look at the physical work environment, equipment, materials, products, etc. that are used.
- Include how the tasks are done.
- Look at injury and incident records.
- Talk to the workers: they know their job and its hazards best.
- Include all shifts, and people who work off site either at home, on other job sites, drivers, teleworkers, with clients, etc.
- Look at the way the work is organized or done (include experience of people doing the work, systems being used, etc).
- Look at foreseeable unusual conditions (for example: possible impact on hazard control procedures that may be unavailable in an emergency situation, power outage, etc.).
- Determine whether a product, machine or equipment can be intentionally or unintentionally changed (e.g., a safety guard that could be removed).
- Review all of the phases of the lifecycle.
- Examine risks to visitors or the public.
- Consider the groups of people that may have a different level of risk such as young or inexperienced workers, persons with disabilities, or new or expectant mothers.

What types of hazards are there?

A common way to classify hazards is by category:

- biological – bacteria, viruses, insects, plants, birds, animals, and humans, etc.,
- chemical – depends on the physical, chemical and toxic properties of the chemical,
- ergonomic – repetitive movements, improper set up of workstation, etc.,
- physical – radiation, magnetic fields, temperature extremes, pressure extremes (high pressure or vacuum), noise, etc.,
- psychosocial – stress, violence, etc.,
- safety – slipping/tripping hazards, inappropriate machine guarding, equipment malfunctions or breakdowns.

How do I know what is a hazard?

Another way to look at health and safety in your workplace is to ask yourself the following questions. These are examples only. You may find other items or situations that can be a hazard. List any item that should be examined. During the risk assessment process, the level of harm will be assessed.

What materials or situations do I come into contact with? Possibilities could include:

- electricity
- chemicals (liquids, gases, solids, mists, vapours, etc.)
- temperature extremes of heat or cold (e.g., bakeries, foundries, meat processing)
- ionizing/non-ionizing radiation (e.g., x-rays, ultraviolet (sun) rays)

- oxygen deficiency
- water

What materials or equipment could I be struck by?

- moving objects (e.g., forklifts, overhead cranes, vehicles)
- flying objects (e.g., sparks or shards from grinding)
- falling material (e.g., equipment from above)

What objects or equipment could I strike or hit my body upon, or that part of my body might be caught in, on, or between?

- stationary or moving objects
- protruding objects
- sharp or jagged edges
- pinch points on machines (places where parts are very close together)
- objects that stick out (protrude)
- moving objects (conveyors, chains, belts, ropes, etc.)

What could I fall from? (e.g., falls to lower levels)

- objects, structures, tanks, silos, lofts
- ladders, overhead walkways
- roofs
- trees, cliffs

What could I slip or trip on? (e.g., falls on same level)

- obstructions on floor, stairs
- surface issues (wet, oily, icy)
- footwear that is in poor condition

How could I overexert myself?

- lifting
- pulling
- pushing
- carrying
- repetitive motions

What other situations could I come across?

- unknown/unauthorized people in area
- a potentially violent situation
- working alone
- confined space
- missing/damaged materials
- new equipment/procedure at work site
- fire/explosion
- chemical spill or release

Where can I find more information about hazards?

It may be necessary to research about what might be a hazard as well as how much harm that hazard might cause. Sources of information include:

- Safety Data Sheets (SDSs).
- Manufacturer's operating instructions, manuals, etc.
- Test or monitor for exposure (occupational hygiene testing such as chemical or noise exposure).
- Results of any job safety analysis.
- Experiences of other organizations similar to yours.
- Trade or safety associations.
- Information, publications, alerts, etc. as published by reputable organizations, labour unions, or government agencies.

What if I am new to the workplace?

If you are new to your workplace, to learn about the hazards of your job, you can:

- ask your supervisor
- ask a member of the health and safety committee or your health and safety representative
- ask about standard operating procedures and precautions for your job
- check product labels and safety data sheets
- pay attention to signs and other warnings in your work
- watch for posters or instructions at the entrance of a chemical storage room to warn of hazardous products
- ask about operating instructions, safe work procedures, processes, etc.

CAUSES AND EFFECTS OF RISK ASSESSMENT

Risk Identification

Risk identification determines what might happen that could affect the objectives of the project. It produces a deliverable — the project risk register – that documents the risks and their characteristics.

The risk register is subsequently amended by the qualitative or quantitative risk analysis, risk response, and risk monitoring processes. Risk identification is an iterative process because new risks may become known as the project progresses through its life cycle, previously-identified risks may drop out, and other risks may be updated.

"Risk" Includes Threats and Opportunities

There are two sides to risk: threats and opportunities.

Projects in design have the greatest potential for opportunities because the project is still open to changes. Risk reduction and avoidance are opportunities, as are value analyses, constructability reviews, and innovations in design, construction methods, and materials.

Once a project enters construction, the project objectives (scope, time, and cost) are fixed contractually, so opportunities to save money and time are fewer.

Any changes must be made using a Supplemental Agreement (SA) and only a negative SA such as one resulting from a Value Engineering Change Proposal by the contractor would still afford an opportunity to save money and time.

Otherwise, SAs add cost and/or time to the project. So, the risk management focus during construction is on reducing or eliminating risks.

Identifying Project Risks

When risk management is initially applied to a project, the project risk manager convenes the PRMT to identify and assess risks.

Including causes or effects in a risk register can obscure genuine risks, which may not receive the appropriate degree of attention they deserve.

One way to clearly separate risks from their causes and effects is to use a description with required elements to provide a three-part structured "risk statement": "If

At the risk identification stage, the impacts on cost and time are not analyzed – that happens in

xxxxx (cause) ocurrs, then xxxxx (risk event) may happen, which will harm our xxxx (consequence)."As a result of *<definite cause>*, *<uncertain event>* may occur, which would lead to *<effect on objective(s)>*."

Examples include:

- "If we use an unfamiliar technology (a definite requirement), then unexpected design problems may occur (an uncertain risk), which would result in overspending on the project (an effect on the budget objective)."

- "If we commit to a project design we have never utilized (fact = cause), then we may misunderstand the requirements (uncertainty = risk), resulting in a project which does not meet the performance criteria (contingent possibility = effect on objective)."the qualitative risk analysis or quantitative risk analysis processes.

The team members identify the potential risks (threats and opportunities) using any combination of:

- Brainstorming,
- Challenging of assumptions,
- Looking for "newness" (e.g. new materials, technology, or processes),
- Their knowledge of the project or similar projects,
- Consultation with others who have significant knowledge of the project or its environment,
- Consultation with others who have significant knowledge of similar projects, and
- The experience of project stakeholders or others in the organization.

When the team identifies risks, it should include descriptions of:

- What may happen or not go according to plan,
- What the impacts to the project objectives would be should the risk arise,
- What the assumptions and current status are that support the assessment of the risk,
- What action, if any, has been taken to respond to the risk, and
- What further options might be available for responding to the risk?

The information is entered into the risk register. Each risk is assigned to a member of the PRMT who becomes its Risk Owner. The risk register is reviewed and updated throughout the project.

The project manager, at his/her option, may elicit initial risk registers from the functional units and consolidate the contributions into a single project risk register.

Alternatively, the project risk register may be developed during a PRMT meeting.

MITIGATING RISKS AT JOB SITES

Access to all areas of a project site may not be possible before construction. This makes it difficult to determine environmentally sensitive areas or subsurface information. The team needs to recognize this uncertainty address it in the construction phase.

Some options for addressing the risks from unknown conditions:

1. Plan for the scope of the risk and consider different payment mechanisms, like change orders, to mitigate it.

2. Provide language in the Special Provisions for the contractor to provide access to the job site for the Department's personnel as a first order of work.

3. Provide language in the Special Provisions for the contractor to hold off on ordering materials whose quantity may be impacted by this new information.

4. Provide resources for design personnel to perform a timely design/assessment using the new information.

Examples of Risk Statements

TABLE 4 – EXAMPLE RISK STATEMENTS

Risk Statement	
Design	If the survey is inaccurate or incomplete, then the project's design may have to be revised.
	A design change that is outside the parameters contemplated in the Environmental Document triggers a supplemental EIR which causes a delay due to the public comment period.
Environmental	Potential lawsuits may challenge the environmental report, delaying the start of construction or threatening loss of funding.
	Nesting birds, protected from harassment under the Migratory Bird Treaty Act, may delay construction during the nesting season.
R/W	Due to the complex nature of the staging, additional right of way or construction easements may be required to complete the work as contemplated, resulting in additional cost to the project.
	Due to the large number of parcels and businesses, the condemnation process may have to be used to acquire R/W, which could delay start of construction by up to one year, increasing construction costs.
Construction	Hazardous materials encountered during construction will require an on-site storage area and potential additional costs to dispose.
	Unanticipated buried man-made objects uncovered during construction require removal and disposal, resulting in additional costs.

Entering Data into the Risk Register

At this stage, complete the information in the following risk register columns:

Column	Contents
Risk Name	Provide a title for the risk that can be used to refer to it. You will expand upon this in the risk description.
Status	Select "Active" or "Retired." A risk is retired when it has no further possibility of impacting the project.
Description	Write a complete description of the event and its potential impacts on the project if this risk were to occur. See Section 3-2 for the structure of the risk statement.
Probability	The likelihood that the risk event will happen.

Impact	If the risk event does occur, what will the effect be (positive or negative) on cost, time, scope and/or quality?
Response Type	Select how the PM or PMRT has chosen to respond to the risk: Avoid, accept, mitigate, transfer, exploit, enhance or share. See chapter 7 for definitions of risk response strategies.
Response Action	List how the risk will be dealt with.
Responsible Person	Enter the name of the PRMT member responsible for this risk.
Residual probability/impact	If the risk action is followed, how has the probability/impact changed?
Contingency	How much time or dollars need to be set aside for this risk on the project? This amount should be carried into TPCE or schedule as extra. For major/moderate projects, this amount may be calculated using a Monte Carlo simulation. For smaller projects, the PRM or PM may simply do research on material costs, for example, and input an estimate.

Last Updated	Enter the date the risk was created.
Next Review Date	Enter the date when the risk register will be updated again.

CAUSES AND EFFECTS OF INCIDENTS

INTRODUCTION

Most managers do not understand how much incidents and other loss-producing events really cost. Wearing the blinders of traditional thinking in the area of incidents, they are likely to see only the costs of medical treatment and workers' compensation.

What is worse, they may accept these as the inevitable costs of "doing business", or assume that incident costs are borne by the insurance carrier. Even fewer managers understand that the same factors, which are creating incidents, are also creating production losses as well as quality and cost problems.

To understand the causative factors of incidents is to take a giant step in the control of all losses.

The safety records of leading organisations prove that incidents are not the inevitable cost of getting the work done. Also, insurance companies are not charitable organisations. The amounts they pay out, plus their administrative costs and profits, are charged back to the insured in higher premiums based on the incident experience of each organisation.

In addition, it has been demonstrated by numerous organisations that the cost of medical insurance and workers' compensation, as large as they are, are only a small part of the real costs of incidents.

However, more is involved than just understanding the costs of incidents and the sizeable negative impact on profit or services rendered. A proper understanding of incident causation is critical to the development of appropriate controls.
For instance, managers who believe that most incidents are caused by "carelessness" are likely to resort to punishment or incentive programs to get people to be "more careful". A very likely result is that incident problems are covered up rather than solved.

Managers who believe that incidents are "freak" occurrences are likely to attempt to protect themselves by buying more insurance, only to discover that it rarely, if ever, pays for the full losses involved.

OBJECTIVES

On completing this module the candidates will be able to:

DEFINE:

2 Incident

3 Incident Ratio Study

4 Loss Causation Model

DESCRIBE:

1. Incident Ratio Study

- Loss Causation Model

PRACTICAL DEFINITIONS

To understand the sequence of events that can lead to a loss, it is essential to understand what one is trying to prevent or control. An INCIDENT may be defined as an undesired event that could or does results in harm to people, damage to property or loss to process.

It is usually the result of contact with a substance or a source of energy (chemical, thermal, acoustical, mechanical, electrical, etc.) above the threshold limit of the body or structure. There are three important aspects of this definition.

Incident an undesired event that could or does results in harm to people, damage to property or loss to process

First, it doesn't limit the human results to "injury", but says "harm to people". This includes both injury and illness, as well as adverse mental, neurological or systemic effects resulting from an exposure or circumstances encountered in the course of employment.

Second, this definition does not confuse "injury" with "incident". They are not the same. Injuries and illnesses result from incidents. But not all incidents result in injuries or illnesses. this distinction is critical to significant progress in safety and health.

The occurrence of the incident itself is controllable. The severity of an injury that results from an incident is often a matter of chance.

Incidents result from contact with a substance or source of energy above the threshold limit of the body or structure

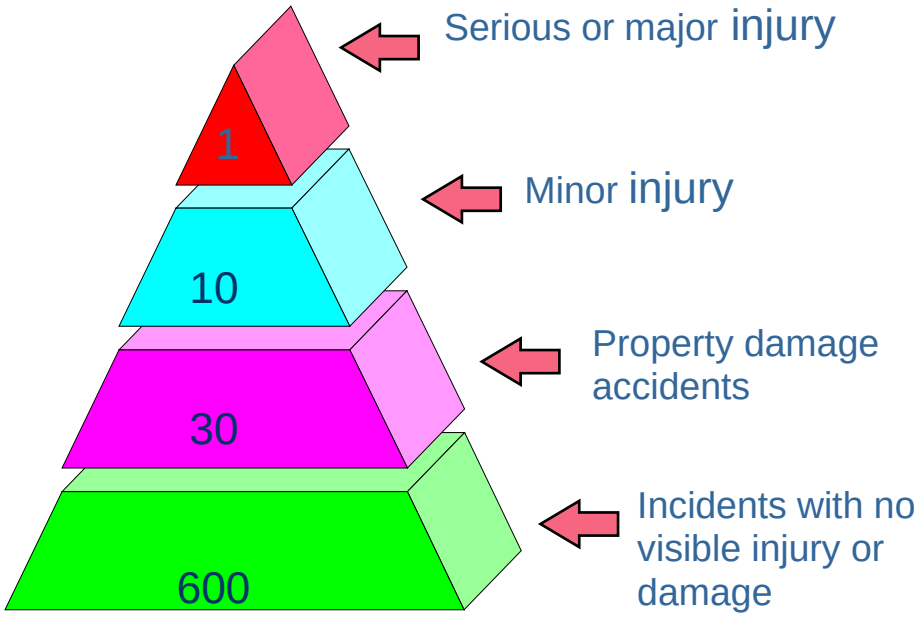
Another term frequently used in safety and health is the word NEAR MISS INCIDENT. An incident with high potential for harm (HIPO) should be investigated as thoroughly as an incident. In this context, then, an near miss incident is an undesired event which, under slightly different circumstances, could have resulted in harm to people, damage to property or loss to process.

A number of companies with more sophisticated programs refer to every undesired event as an incident to permit a broader loss control coverage in their programs. Certain no-loss events are referred to as high potential in order that the same special attention be paid to them as to serious loss producing events.

A third important definition is of the word SAFETY. It is usually defined as freedom from incidents or the condition of being safe from pain, injury or loss. However, a more functional definition is control of incidental loss. This definition relates to injury, illness, property damage and loss to process.

It includes both preventing incidents and keeping losses to a minimum when incidents do occur. It also related to the function of control in the management system.

SAFETY
Control of incidental loss.

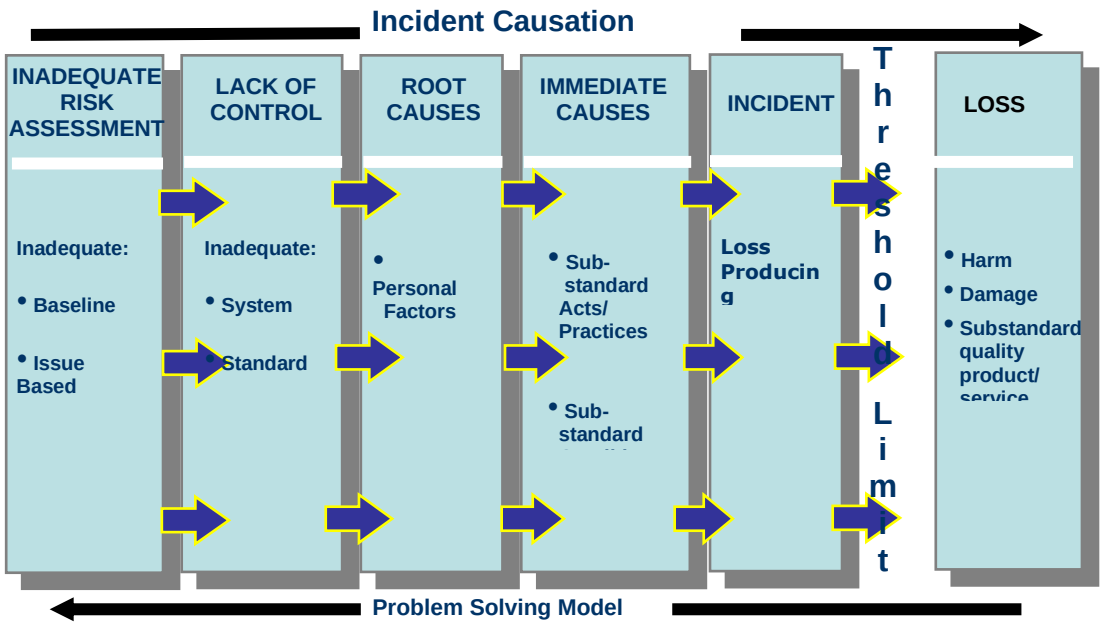


INCIDENT RATIO STUDY

LOSS CAUSATION MODELS

Numerous incident and loss causation models have been introduced during recent years. A large percentage is complex and difficult for many to understand and remember.

While the loss causation model shown is relatively simple, it contains the necessary key points that enable the user to understand and retain the critical few facts important to the control of the vast majority of incidents and loss and management problems.
It is current and consistent with what safety and loss control leaders throughout the world are saying about incident and loss causation.



LOSS

LOSS
PEOPLE PROPERTY PROCESS

The result of an incident is loss. As reflected in our incident definition, the most obvious losses are harm to people, property or process.

Implied and important related losses are "performance interruption" and "profit reduction.". So there are losses involving people, property, process and ultimately, profit.

Once the sequence has occurred, the type and degree of loss are somewhat a matter of chance. The effect may range from insignificant to catastrophic, from a scratch or dent to multiple fatalities or loss of a plant.

The type and degree of loss depend partly on fortuitous circumstances and partly on the actions taken to minimise loss at this stage of the sequence include prompt and proper first aid and medical care, fast and effective firefighting, prompt repair of damaged equipment and facilities, efficient implementation of emergency action plans and effective rehabilitation of people for work.

Nothing is more important or more tragic then the human aspect of incidental loss: injury, pain, sorrow, anguish, loss of body parts or functions, occupational illness, disability, death.

The best-known way to minimise these is to use both the humane aspects and the economic aspects to motivate control of the incidents that lead to the losses.

Whether or not people are hurt, incidents do cost money – and lots of it! And the injury or illness costs are a relatively small part of the total costs.

INCIDENT / CONTACT

INCIDENT
CONTACT WITH ENERGY OR SUBSTANCE

This is the event that precedes the "loss" – the contact that could or does cause the harm or damage.

When potential causes of incidents are permitted to exist, the way is always open for a contact with a source of energy above the threshold limit of the body or structure.

As an example, a flying or moving object involves kinetic energy, which transfers to the body or structure it hits or contacts.

If the amount of energy transferred is too much, it causes personal harm or property damage. This is true not only of kinetic energy but also electrical energy, acoustic energy, thermal energy, radiant energy and chemical energy.

Here are some of the more common types of energy transfers:

1. Stuck against (running or bumping into)
2. Stuck by (hit by moving object)
3. Fall to lower level (either the body falls or the object falls and hits the body)
4. Fall on same level (slip and fall, tip over)
5. Caught in (pinch and nip points)
6. Caught on (snagged, hung)
7. Caught between (crushed or amputated)
8. Contact with (electricity, heat, cold, radiation, caustics, toxins, noise)
9. Overstress / overexertion / overload

IMMEDIATE CAUSES

IMMEDIATE CAUSES
SUB-STANDARD ACTS AND CONDITIONS

The "immediate causes" of incidents are the circumstances that immediately precede the contact. They usually can be seen or sensed.

Frequently they are called "unsafe acts" (behaviours which could permit the occurrence of an incident) and "unsafe conditions" (circumstances which could permit the occurrence of an incident).

Modern managers tend to think a bit broader, and more professionally, in terms of substandard practices and substandard conditions (deviations from an accepted standard of practice).

This line of thinking has distinct advantages:

- It relates practices and conditions to a standard, a basis for measurement, evaluation and correction;
- It somewhat minimises the finger-pointing stigma of the term “unsafe act”; and
- It broadens the scope of interest from incident control to loss control, encompassing safety, quality, production, and cost control.

Substandard practices and conditions usually are seen in one or more of the following forms:

SUBSTANDARD PRACTICES	SUBSTANDARD CONDITIONS
• Operating equipment without authority • Failure to warn • Failure to secure • Operating at improper speed • Making safety devices inoperable • Removing safety devices • Using defective equipment • Using equipment improperly • Failing to use personal protective equipment properly • Improper loading • Improper placement • Improper lifting • Improper position for task • Servicing equipment in operation • Horseplay • Under influence of alcohol and/or other drugs.	• Inadequate guards or barriers • Inadequate or improper protective equipment • Defective tools, equipment or materials • Congestion or restricted action • Inadequate warning systems • Fire and explosion hazards 10. Poor housekeeping; disorderly workplace •Hazardous environmental conditions; gases, dusts, smokes, fumes, vapours •Noise exposures 1. Radiation exposures 1. High or low temperature exposures 1. Inadequate or excessive illumination **1.** Inadequate ventilation**.**

It is essential to consider their practices and conditions only as immediate causes or symptoms, and to do a thorough job of diagnosing the diseases behind the symptoms.

If you only treat the symptoms, they will occur again and again. You need to answer the questions:

... Why did that substandard practice occur?
... Why did that substandard condition exist?
... What failure in our supervisory / management system permitted that practice or condition?

If you dig deep enough, the answers will point the way to more effective control. To solve loss control performance problems, you must at the basic or root causes.

BASIC CAUSES

BASIC CAUSES
PERSONAL FACTORS
JOB FACTORS

Basic causes are the diseases or real causes behind the symptoms; the reasons why the substandard acts and conditions occurred; the factors that, when identified, permit meaningful management control.

Often, these are referred to as root causes, real causes, indirect causes, underlying or contributing causes.

This is because the immediate causes (the symptoms, the substandard acts and conditions) are usually quite apparent, but it takes a bit of probing to get at basic causes and to gain control of them.

Basic causes also help explain why substandard conditions exist. Equipment and materials, which are inadequate or hazardous, will be purchased if there are not adequate standards, and if compliance with standards is not managed.

Unsafe structures and work process layouts will be designed and built if there are not adequate standards and compliance for design and construction. Equipment will wear out and produce a substandard product, create waste or break down and cause an incident if that equipment is not properly selected, properly used and properly maintained.

Just as it is helpful to consider two major categories of immediate causes (substandard practices and substandard conditions), so is it helpful to think of basic causes in two major categories:

PERSONAL FACTORS

11. Inadequate capability
    - Physical / Physiological
    - Mental / Psychological
12. Lack of knowledge
13. Lack of skill
14. Abuse or misuse
15. Stress
    - Physical / Physiological
    - Mental / Psychological
16. Improper motivation

JOB FACTORS (WORK ENVIRONMENT)

17. Inadequate leadership and/or supervision
18. Inadequate engineering
19. Inadequate purchasing
20. Inadequate maintenance
21. Inadequate tools, equipment, materials
22. Inadequate work standards
23. Wear and tear

Basic causes are shown in more detail below which gives specific examples of each cause.

BASIC CAUSES OF LOSS

PERSONAL FACTORS	
24. Inadequate Physical / Physiological Capability - inappropriate height, weight, size, strength, each, etc. - restricted range of body movement - limited ability to sustain body positions - substance sensitivities or allergies - sensitivities to sensory extremes (temperature, sound, etc.) - vision deficiency - hearing deficiency - other sensory deficiency (touch, taste, smell, balance) - respiratory incapacity - other permanent physical disabilities - temporary disabilities 25. Inadequate Mental / Psychological Capabilities - fears and phobias - emotional disturbance - mental illness - intelligence level - inability to comprehend - poor judgement - poor co-ordination - slow reaction time - low mechanical aptitude - low learning aptitude	27. Mental or Psychological Stress - emotional overload - fatigue due to mental task load or speed - extreme judgement / decision demands - routine, monotony, demand for uneventful vigilance - extreme concentration / perception demands - "meaningless" or "degrading" activities - confusing directions - conflicting demands - preoccupation with problems - frustration - mental illness 28. Lack of Knowledge - lack of experience - inadequate orientation - inadequate initial training - inadequate update training - misunderstood directions Lack of Skill - inadequate initial instruction - inadequate practice - infrequent performance - lack of coaching

- memory failure 26. Physical or Physiological Stress - injury or illness - fatigue due to task load or duration - fatigue due to lack of rest - fatigue due to sensory overload - exposure to health hazards - exposure to temperature extremes - oxygen deficiency - atmospheric pressure variation - constrained movement - blood sugar insufficiency - drugs	30. Improper Motivation - improper performance is rewarding - proper performance is punishing - lack of incentives - excessive frustration - inappropriate aggression - improper attempt to save time or effort - improper attempt to avoid discomfort - improper attempt to gain attention - inappropriate peer pressure - improper supervisory example - inadequate performance feedback - inadequate reinforcement of proper behaviour - improper production incentives

JOB FACTORS	
31. Inadequate Leadership and/or Supervision **- unclear or conflicting reporting relationships** **- unclear or conflicting assignment of responsibility** **- improper or insufficient delegation** **- giving inadequate policy, procedure, practices or guidelines** **- giving objectives, goals or standards that conflict** **- inadequate work planning or programming** **- inadequate instructions, orientation and/or training** **- providing inadequate reference documents, directives and guidance publications** **- inadequate identification and evaluation of loss exposures** **- lack of supervisory / management job knowledge** **- inadequate matching of individual qualifications and job / task requirements**	**- improper transporting of material** **- inadequate identification of hazardous items** **- improper salvage and/or waste disposal** **35. Inadequate Maintenance** **- inadequate preventive** **... assessment of needs** **... lubrication and servicing** **... adjustment / assembly** **... cleaning or resurfacing** **- inadequate reparative** **... communication of needs** **... scheduling of work** **... examination of units** **... part substitution.** **36. Inadequate Tools and Equipment** **- inadequate assessment of needs and risks** **- inadequate human factors / ergonomics considerations** **1. inadequate standards or specifications**

- inadequate performance measurement and evaluation - inadequate or incorrect performance feedback. 32. Inadequate Engineering - inadequate assessment of loss exposures - inadequate consideration of human factors / ergonomics - inadequate standards, specifications and/or design criteria - inadequate monitoring of construction - inadequate assessment of operational readiness - inadequate monitoring of initial operation - inadequate evaluation of changes. 33.Inadequate Purchasing - inadequate specifications on requisitions - inadequate research on materials / equipment - inadequate specifications to vendors - inadequate mode or route of shipment - inadequate receiving inspection and acceptance - improper handling of materials - improper storage of materials 34. Wear and Tear 1. inadequate planning of use 2. improper extension of service life 3. inadequate inspection and/or monitoring 4. improper loading or rate of use - inadequate maintenance - use by unqualified or untrained people - use for wrong purpose	2. inadequate availability 3. inadequate adjustment / repair / maintenance - inadequate salvage and reclamation - inadequate removal and replacement of unsuitable items. 37. Inadequate Work Standards - inadequate development of standards ... inventory and evaluation of exposures and needs ... co-ordination with process design ... employee involvement ... inconsistent standards / procedures / rules. - inadequate communication of standards ... publication ... distribution ... translation to appropriate languages ... reinforcing with signs, colour codes and job aids - inadequate maintenance of standards ... tracking of work flow ... updating ... monitoring use of standards / procedures / rules. 38. Abuse or Misuse ... intentional - condoned by supervision ... unintentional - not condoned by supervision ... intentional ... unintentional

Basic causes are the origins of substandard practices and conditions.

However, they are not the beginning of the cause and effect sequence.

What starts the sequence, ending in loss, is “lack of control”.

LACK OF CONTROL

LACK OF CONTROL
INADEQUATE PROGRAM PROGRAM STANDARDS COMPLIANCE TO STANDARDS

Control is one of the four essential management functions: plan, organise, lead and control.

These functions relate to any manager’s work, regardless of level or title.

Whether the function is administration, marketing, production, quality, engineering, purchasing or safety, the supervisor / leader / manager must plan, organise, lead and control to be effective.

The person who manages professionally knows the safety / loss control program; knows the standards; plans and organises work to meet the standards; leads people to attain the standards; measures performance of self and others; evaluates results and needs; commends and constructively corrects performance.

This is management control. Without it, the incident sequence begins and triggers the continuing causal factors that lead to loss. Without adequate management control, the incident cause and effect sequence is started and, unless corrected in time, leads to losses.

There are three common reasons for lack of control:

1. inadequate system,
2. inadequate system standards, and
3. inadequate compliance with standards.

Inadequate System

A safety / loss control program may be inadequate because of too few program activities. While the necessary program activities vary with an organisation’s scope, nature, and type, significant research and the experience of successful programs in may different companies and countries show the activities below to be the common elements of success.

Many organisations around the world use these as a blueprint for building an adequate safety / loss control management program.

Inadequate System Standards

A common cause of confusion and failure is standards that are not specific enough, not clear enough and/or not high enough. Standards should let people know what is expected of them and permit meaningful measurement of how well they perform in relation to the standards.

Adequate standards are essential for adequate control.

Inadequate Compliance with Standards

Lack of compliance with existing standards is a common reason for lack of control. In fact, most managers agree that this is the single greatest reason for failure to control incident loss. This almost unanimous agreement explains the emphasis found throughout this book on measurements of quantity and quality of efforts in the program.

Correcting these three common reasons for lack of control is a critical management responsibility. Developing an adequate system and standards is an executive function, aided by Supervisors. Maintaining compliance with standards is a supervisory function, aided by executives. It's a management team effort all the way.

MULTIPLE SOURCES - CAUSES - CONTROLS

Management leaders have written thousands of articles through the years on the complex nature of the errors and problems that lead to losses in the business world. A combination of factors or causes comes together under just the right circumstances to bring out these undesired events.

Seldom, if ever, is there a single cause of any management problem, including those involved with safety, production, or quality.

Available information has led management personnel to accept the following conclusions:

1. The incidents that downgrade our businesses are caused: they don't just happen.
1. The causes of loss can be determined and controlled.

In order to better understand the circumstances which lead to the causes of undesired incidents, it would be helpful to consider the four major elements or subsystems in the total business operation that provide their sources. These four elements would include:

1. people,
2. equipment,
3. materials and
4. environment.

All four of these elements must relate or interact properly with each other or problems may be created which could lead to loss. Let's examine each of these elements briefly:

PEOPLE

This element includes management, employees, contractors, customers, visitors, suppliers, the public, the human element. Experience shows that the human element is involved in a large proportion of incident / incident causes. However, "people" does not simply mean "the employees who are involved in the incidents".

The old concept that 85%, or more, of incidents are caused by the faults of workers will come under more and more critical analysis in the light of modern knowledge and experience.

As indicated earlier, there is increasing evidence that at least 80% of the mistakes people make involve things that only management can do something about.
Managing the people element, and the interactions of people with the other elements of the system, is a major means of effective control.

EQUIPMENT

This element includes all the tools and machines that people work near and with: fixed machines, vehicles, materials handling devices, hand tools, protective equipment, personal gear, and so on. These items that people work with are a tremendous source of potential injury and death.

MATERIALS

This element includes raw materials, chemicals and other substances that people use, work with and process. they are another major source of incident loss. In many companies, material handling injuries account for 20 to 30 percent of all their injuries.

Likewise, much property damage involves materials that spilled, corroded, burned or exploded.
No manager is doing a satisfactory job of controlling incident losses unless he or she is effectively managing the safe, proper handling of materials.

ENVIRONMENT

This element includes all parts of the surroundings; buildings and enclosures that surround people, equipment and materials; fluids and air which surround other elements; chemical hazards such as mists, vapours, gases, fumes and dusts; weather and atmospheric phenomena; biological hazards such as moulds, fungi, bacteria and viruses; and physical conditions such as light noise, heat, cold pressure, humidity and radiation.

This subsystem of the business organisation represents the source of causes of an ever-increasing number of diseases and health-related conditions. It not only is involved in incidents and occupational illness problems, but also in other losses such as absenteeism, poor quality products and services, and loss of productivity.

Of course, more and more attention must be given to the external or public environment that can be so adversely affected by air, steam and soil pollution from the occupational establishment.

The four major elements or subsystems in the total organisational system (People, Equipment, Material, and Environment), individually or in their interactions, are the major sources of causes that contribute to incidents and other loss-producing events.

All four should be carefully considered when investigating such incidents and especially, when developing and implementing corrective and preventive measures. Effective managers manage the total system

THE CONCEPT OF MULTIPLE CAUSES

Among the practical principles of professional management is the Principles of Multiple Causes: problems and loss-producing events are seldom, if ever, the results of a single cause.

This is an essential principle for safety / loss control management. One should never assume that there is a single cause of an incident of incident.

THREE STAGES OF CONTROL

These are grouped into three major categories or stages of control:

1. pre-contact,
2. contact, and
3. post-contract.

Pre-Contact Control

This is the stage that includes everything we do to develop and implement a program to avoid the risks, prevent the losses from occurring, and plan actions to reduce loss if and when contacts occur.

Pre-contact control is the most fruitful stage. This is where we develop an optimum program, establish optimum standards, maintain effective performance feedback, and manage compliance with performance standards.

The goal here is the PREVENTION part of control. Pre-contact control is the goal of most of this book.

Contact Control

Incidents usually involve contact with a source of energy or substance above the threshold limit of the body or structure. Many control measures take effect at the point and time of contact, by reducing the amount of energy exchange or harmful contact.

The contact stage is where the incident occurs that may or may not result in loss, depending on the amount of energy or substance involved.

Effective controls keep the exchange at a minimum, resulting in minor rather than major losses, and "close calls" rather than incident losses. These measures do not prevent the contacts or incidents, but they do contribute significantly to the control of losses.

Post-Contact Control

After the incident or "contact", the extent of losses can be controlled in many ways, such as:

- implementation of the emergency action plans
- proper first aid and medical care for people
- rescue operations
- fire and explosion control
- removal of damaged equipment, materials and facilities from use until repaired
- prompt repair of damaged equipment, materials and facilities
- prompt ventilation of the air-polluted workplace
- effective cleanup of spills
- compensation claims control

- liability claims control
- salvage and waste control measures to reclaim all possible value from damaged items
- prompt and effective rehabilitation of injured workers to a productive life

Post-contact controls do not prevent the incidents, but they minimise the losses. They can mean the difference between injury and death, between reparable damage and total loss, between a complaint and a lawsuit, between business interruption and business closing.

Meaning by preventative, corrective and contingency actions

Corrective Actions

Corrective actions can differ depending on the root cause of the accident. If a driver was drunk he should be included in a treatment program and his driving privileges should be revoked or limited. Similar treatment should be applied in the case of speeding.

If a cause of the accident was a bad road infrastructure it should be repaired – road markings should be restored, road signs should be replaced, a new layer of asphalt may be needed, etc.

The goal of **corrective actions** is to remove the root cause and prevent a concrete problem from ever happening again. **Corrective actions** are directed to a concrete event that happened in the past. When the right corrective actions are taken all root causes of the problem should be eliminated.

Preventive Actions

Preventive actions are proactive and oriented towards a potential problem in the future. They improve a process or a product to prevent a problem from ever happening. Some of the **preventive actions** related to traffic safety could be:

– increasing awareness of the harmful effects of alcohol and drugs,

– high penalties for driving too fast or driving drunk,

– replacing dangerous cross intersections with roundabouts

– informational videos about the most common driving mistakes and difficulties, like incorrect lane changing, insufficient safety distance, safe overtaking, safe driving in tunnels, driving in bad weather conditions, etc.

Often, concrete problems encourage us to think about other related problems that could arise. A concrete problem could encourage us to think if the same causes could apply to problems in related products or processes.

Preventive actions remove causes for a potential problem and prevent it and related problems from ever happening.

To summarize the **difference between containment, corrective and preventive actions**:

With containment actions we try to limit a concrete problem's extent and establish normal operations. Corrective actions are retrospective and should prevent the problem from ever happening again.

Preventive actions are proactive solutions to improve processes and products and prevent similar potential problems from ever happening.

Contingency Plans: An Essential Quality Management System Risk Tool

By Mark Durivage, Quality Systems Compliance LLC

Probably the biggest concern for anyone implementing, deploying, and maintaining a quality management system (QMS) is the integration of risk-based thinking. While the concept of risk management is not new, previous practice was more reactionary, primarily focused on detection after the fact, root cause analysis, corrective actions, and preventing recurrence of the failure.

Contemporary thinking places the emphasis on considering risks up front (prevention) and having a solid approach to address risk in planning, managing, and driving actions.

This article will present the concept of contingency planning and introduce some considerations that can be utilized to develop an effective contingency plan.

Definitions and Background

Several ISO standards, FDA regulations, and international guidance documents provide direction for successfully implementing, maintaining, and sustaining an effective and robust QMS regardless of its type, size, or the products and services it provides.

The following requirements speak directly and indirectly about contingency planning.

ISO 9001:2015 Quality management systems — Requirements

4.4.1 The organization shall establish, implement, maintain and continually improve a quality

management system, including the processes needed and their interactions, in accordance with the
requirements of this International Standard.
The organization shall determine the processes needed for the quality management system and their
application throughout the organization, and shall:

d) determine the resources needed for these processes and ensure their availability;

f) address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

5.4.2 Quality management system planning

Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements

given in 4.1, as well as the quality objectives;

b) the integrity of the quality management system is maintained when changes to the quality

management system are planned and implemented.

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of

product realization shall be consistent with the requirements of the other processes of the quality

management system.

The organization shall document one or more processes for risk management in product realization.

Records of risk management activities shall be maintained (see 4.2.5).

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order

to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential

problems.

The organization shall document a procedure to describe requirements for:

a) determining potential nonconformities and their causes;

b) evaluating the need for action to prevent occurrence of nonconformities;

c) planning and documenting action needed and implementing such action, including, as appropriate,

updating documentation;

d) verifying that the action does not adversely affect the ability to meet applicable regulatory

requirements or the safety and performance of the medical device;

e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

21 CFR 211.100 Written procedures; deviations

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart.

These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

21 CFR 820.100 Corrective and preventive action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

Identifying The Elements Of A Contingency Plan

One of the best tools to identify which elements should be considered in a contingency plan is the cause-and-effect diagram, better known as the fishbone diagram due to its resemblance to the bones of a fish.

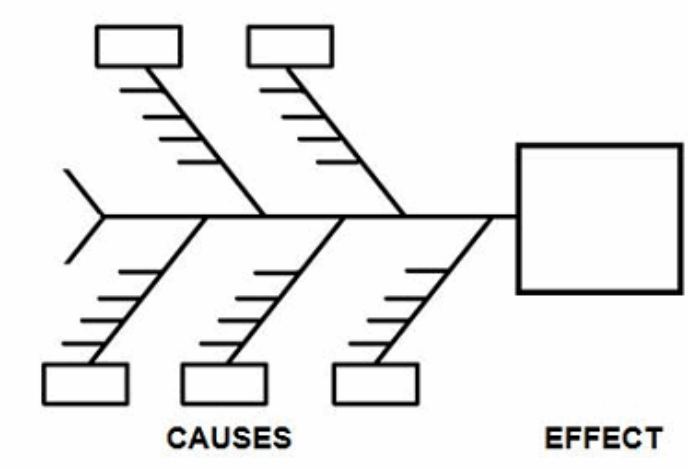


Figure 1: *Example cause-and-effect diagram (fishbone diagram)*

Brainstorming is a method for generating many creative ideas in a short period of time and can help develop a list of which items should be considered for contingency planning. Brainstorming is conducted by recording ideas about a topic.

Each person is asked for an idea in turn, and the session ends when there are no more ideas. The ideas (little horizontal lines) can be generated for each cause (boxes) on the cause-and-effect diagram (see Table 1 for example causes).

Once the brainstorming session is completed, an affinity diagram is used to organize ideas into their natural relationships.

There are many causes for consideration when constructing a cause-and-effect diagram, including business continuity, equipment, facilities, geography, man-made disasters, materials, methods natural disasters, people, policies, procedures, and technology.

This list is not all-inclusive and should be based upon an organization's risk acceptance determination threshold, industry practice, guidance documents, and regulatory requirements.

Table 1: Example Contingency Plan Considerations

Causes	Considerations
Business continuity	Succession plan, ownership
Equipment	Breakdowns, availability, capability
Facilities	Capacity, access, power outages, fire, flood
Geography	Earthquakes, tsunamis, floods
Man-made disasters	Terror attacks, bomb threats
Materials	Availability, obsolescence, compliance
Methods	Safety, compliance, capabilities
Natural disasters	Hurricanes, tornadoes, floods, droughts, blizzards, wildfires
People	Labor shortages, strikes, pandemics
Policies	Compliance
Procedures	Written, repeatable

With any QMS, there are always many needs and limited resources. One possible method to help determine where the contingency planning resources should be focused is shown in Figure 2.

The risk matrix in Figure 2 considers the impact and the likelihood of an occurrence.

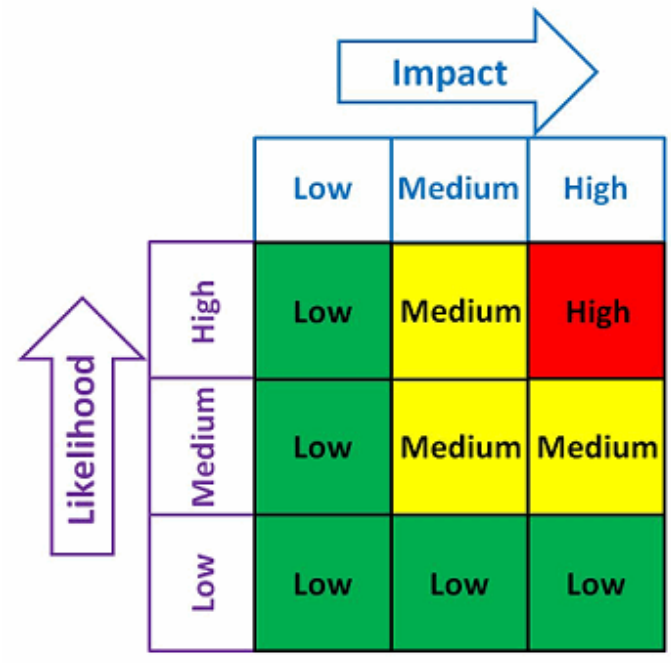


Figure 2: *Example risk matrix*

Example impact and likelihood definitions are shown in Table 2. Contingency plans can be developed based upon the indicated level of risk, placing more emphasis and resources on those issues that are high- and medium-risk and less emphasis and resources on those issue that are low-risk.

Table 2: Example Impact And Likelihood Definitions

Impact Definition	
High	Impacts safety, involves noncompliance with government regulations, and/or disruption of goods and services to end users.
Medium	Interruption of goods and services to end users.
Low	End users will probably not notice the failure.
Likelihood	
High	Certain to fail
Medium	Occasional failure likely
Low	Failure unlikely

Contingency Plans

Once the causes and their levels of risk have been determined, it is time to develop the contingency plan. Contingency plans should include a notification and communication plan. They should also include evacuation routes and assembly points where applicable.

Contingency plans may indicate the need for backup suppliers, alternative/additional equipment, additional facilities, special insurance, contracts with temporary staffing services, etc. Again, I would like to emphasize that the level of planning and detail should be correlated with the level of risk associated with the event.

Workplace Hazard Control Strategies:

Hazard control refers to the program or process used to establish preventative and corrective measures as the final stage of hazard recognition, assessment and control.

The goal is to eliminate, reduce, or control hazards so as to minimize injuries and losses, including accidents, property damage, and time lost.

Three basic levels of intervention exist. They include pre-contact controls, contact controls, and post contact controls.

Pre-contact controls are controls that are put in place in a preemptive fashion in anticipation of specific hazards. The construction of buildings and other structures according to provincial building codes is but one example of a pre-contact control.

Contact controls are controls designed to address identified hazards in such a way that these occupational hazards can be prevented from becoming worse.

Post contact controls involve consequence management steps such as the medical inputs, clean up operations, hazardous occurrence investigations and new investments in corporate safety that typically follow an accident that lead to a workplace injury or fatality.

Controls at each of these three levels may comprise of engineering controls, administrative controls, control by substitution, as well as control through the assignment of personal protective equipment to potentially impacted personnel.