AN OVERVIEW OF HAZARD IDENTIFICATION AND RISK ANALYSIS

ASQ OTTAWA VALLEY SECTION

CHAITANYA BALIGA, ASQ- CQA, CMQ/OE,CSSGB

DEPUTY REGIONAL DIRECTOR, ASQ CANADA AND GREENLAND REGION

PAST CHAIR, ASQ TORONTO SECTION

PAST CHAIR, ASQ SOCIAL RESPONSIBILITY TECHNICAL COMMUNITY

JUNE 16, 2026

PRESENTER DISCLAIMER

- THIS PRESENTATION IS MADE AT THE REQUEST OF AMERICAN SOCIETY OF QUALITY (ASQ) OTTAWA VALLEY.

- **THE INFORMATION PROVIDED IS ONLY INTENDED TO BE GENERAL SUMMARY INFORMATION. IT IS NOT INTENDED TO TAKE THE PLACE OF EITHER THE WRITTEN LAW OR REGULATIONS.**

- THE INFORMATION PROVIDED AND OPINIONS EXPRESSED DURING THIS PRESENTATION ARE THOSE OF THE PRESENTER AND ARE NOT THE POSITION OF AND MAY NOT BE ATTRIBUTED TO ANY OTHER ORGANIZATION.

LEARNING OBJECTIVES

1. QUALITY RISK MANAGEMENT
2. RELATIONSHIP BETWEEN HARM, HAZARD AND HAZARDOUS SITUATION
3. HAZARD IDENTIFICATION
4. HAZARD /RISK IDENTIFICATION APPROACH
5. RISK ANALYSIS
6. RISK ASSESSMENT MATRIX

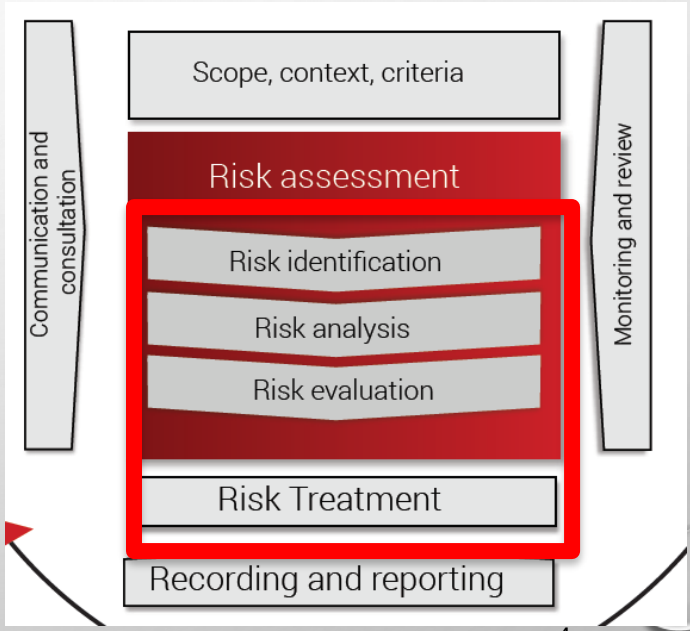
"In the beginner's mind there are many possibilities, but in the expert's there are few"
— **Shunryu Suzuki,** Zen Mind, Beginner's Mind: Informal Talks on Zen Meditation and Practice

RISK ASSESSMENT

A risk narrative is the starting point for any assessment and is simply a way to identify and depict a specific risk.

Risk Assessment = Hazard/Risk Identification + Risk Analysis

- categorizing hazard
- consequences
- likelihood
- final risk.



Risk assessment can be a

‘*Very straightforward process based on judgement requiring no specialist skills or complicated techniques*.’

This approach is commonly known as **qualitative or subjective risk assessment.**

MAJOR HAZARDS

- MAJOR HAZARDS ASSOCIATED WITH COMPLEX CHEMICAL OR NUCLEAR PLANTS, MAY '*WARRANT THE NEED OF SUCH TECHNIQUES AS* ***QUANTITATIVE*** *RISK ASSESSMENT*'.
- IN QUANTITATIVE RISK ASSESSMENT **(QRA)** A **NUMERICAL ESTIMATE** IS MADE OF THE PROBABILITY THAT A DEFINED HARM WILL RESULT FROM THE OCCURRENCE OF A PARTICULAR EVENT.

HAZARD vs RISK

A HAZARD is something that has the potential to harm you

RISK is the likelihood of a hazard causing harm

QUALITY RISK MANAGEMENT

- **HAZARD IDENTIFICATION** IS A SYSTEMATIC USE OF INFORMATION TO IDENTIFY HAZARDS REFERRING TO THE RISK QUESTION OR PROBLEM DESCRIPTION.

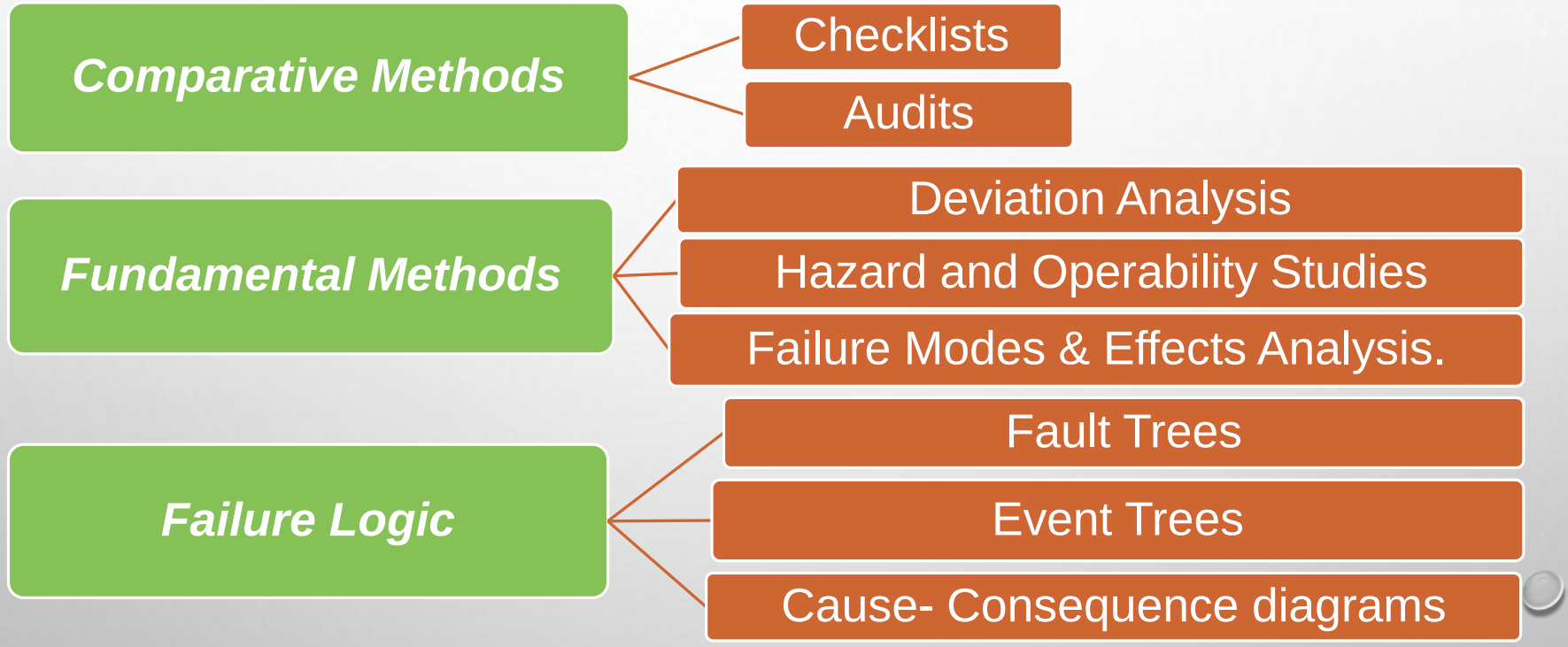
- INFORMATION CAN INCLUDE HISTORICAL DATA, THEORETICAL ANALYSIS, INFORMED OPINIONS, AND THE CONCERNS OF STAKEHOLDERS.

THREE FUNDAMENTAL QUESTIONS

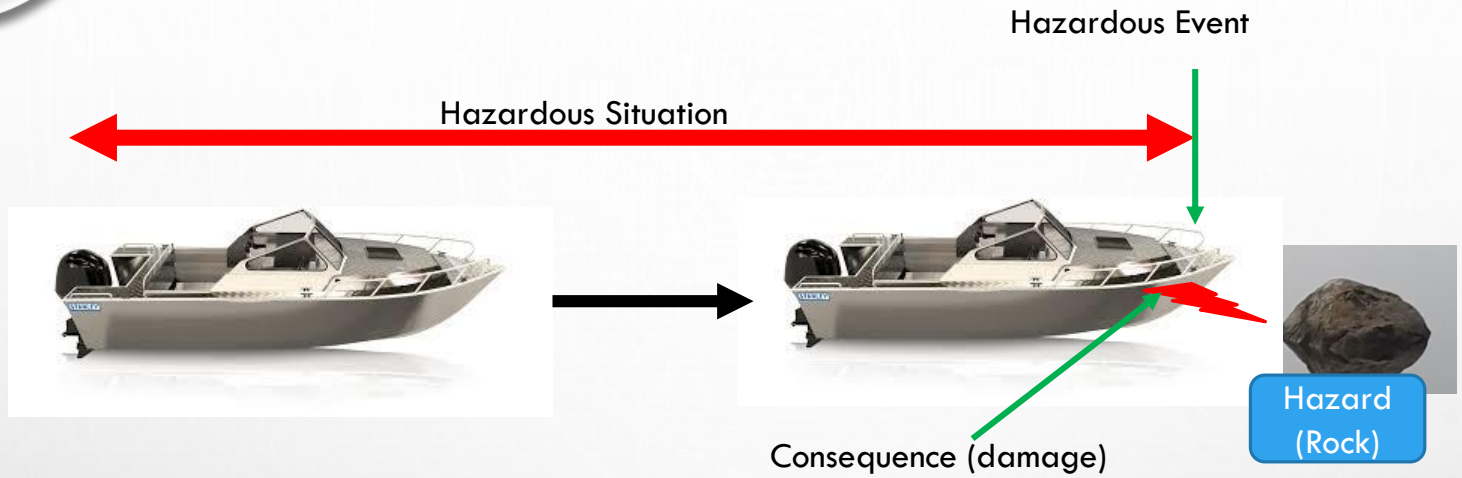
1. **WHAT MIGHT GO WRONG? – HAZARD IDENTIFICATION**
2. WHAT IS THE LIKELIHOOD (PROBABILITY) IT WILL GO WRONG?
3. WHAT ARE THE CONSEQUENCES (SEVERITY)?

HAZARD IDENTIFICATION

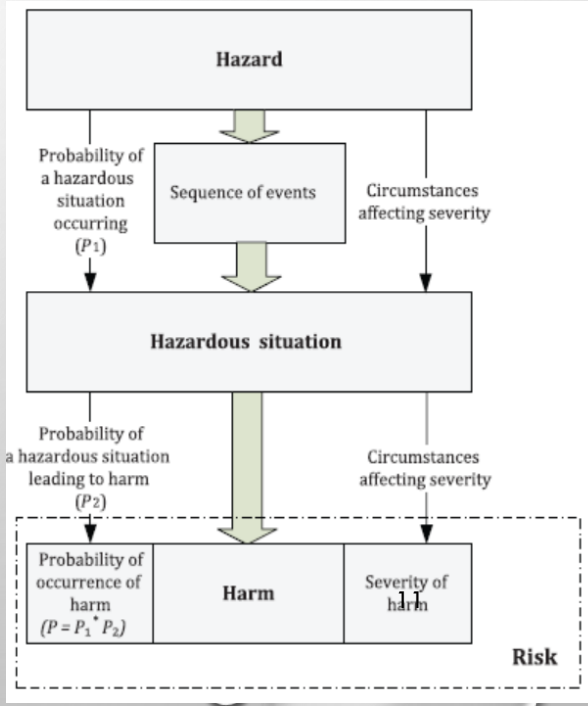
Hazard : *The potential to cause harm. Harm including ill health and injury, damage to property, plant, products or the environment, production losses or increased liabilities.*



UNDERSTANDING HAZARD AND HAZARDOUS SITUATION

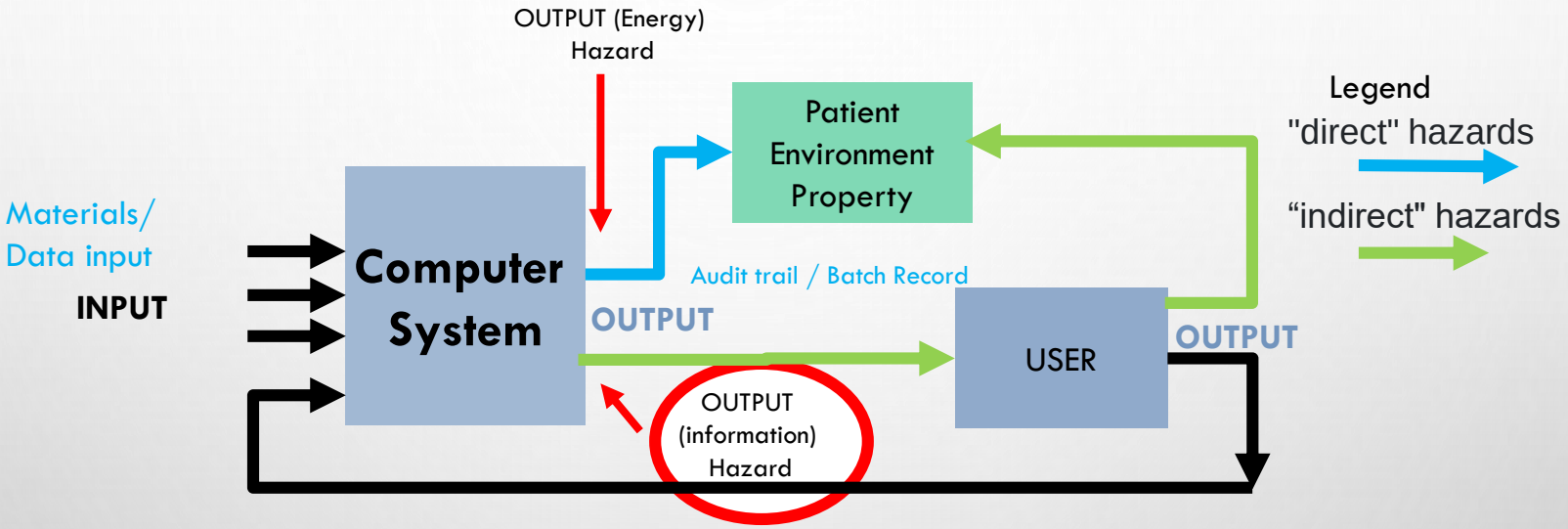


- IDENTIFY A PRODUCT/SYSTEM (BOAT)
- ***REMEMBER : THREE FUNDAMENTAL QUESTIONS :***
- IDENTIFY HAZARD (ROCK) –
- 1. WHAT MIGHT GO WRONG? – HAZARD IDENTIFICATION
- IDENTIFY HAZARDOUS EVENT (DAMAGE TO BOAT)
- IDENTIFY HAZARDOUS SITUATION (INJURY)



HAZARD ANALYSIS - APPROACH

- FOR EXAMPLE DATA INTEGRITY



Hazard Identification:

1. Data loss due to overwriting of the data once the memory is full in the Computer System or data loss in other form
2. Data retrieval – corruption of data when extracted into Batch Record system

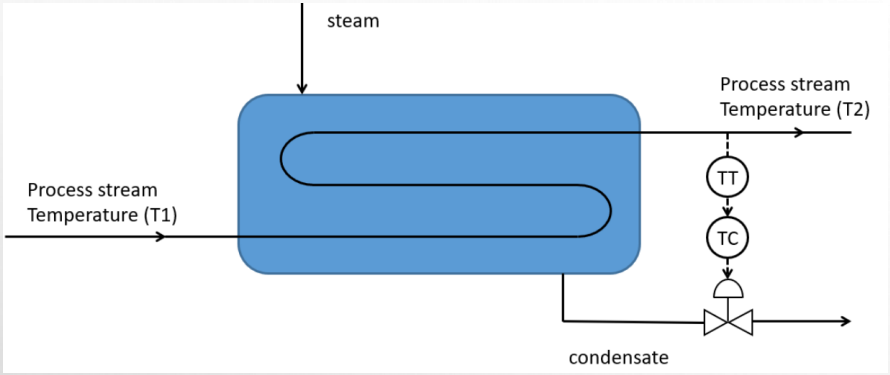
Note: Both the Direct and Indirect Output are potential sources of Harm

TOOLS FOR LINKING HAZARD, SEQUENCE FOR EVENTS AND HAZARDOUS SITUATION LEADING TO HARM

Quality Attribute / Product Requirement	Hazard	Sequence of Events	Hazardous Situation	Harm
Data Integrity	Data Loss	Overwriting of the data once the memory is full in the Computer System	Incorrect Data transfered to the next processing	Data corruption leading to Potential loss to consumer
	Identify the hazard		Identify the hazardous situation	

HAZARD IDENTIFICATION, HAZARDOUS SITUATION, HAZARDOUS EVENT LEADING TO HARM

Identify a Product/System



Identify Hazard

Identify Hazardous Event

Identify Hazardous Situation

HAZARD IDENTIFICATION USING THE STRUCTURED WHAT-IF TECHNIQUE (SWIFT).

A HAZARD IDENTIFICATION takes a "1000 foot" view of an overall SYSTEM and considers potential risks related to it.

The Structured What-If Technique (SWIFT).

SWIFT is a flexible, high-level risk identification technique that can be used on a standalone basis, or as part of a staged approach to make more efficient use of bottom-up methods like FMEA.

SWIFT - PLAN

Prepare the guide words:	• Select a set of guide words/rules based on system / process under consideration
Assemble the team	• Process Owner • SME • Stakeholders
Background	• Why perform risk assessment
Articulate the purpose	• Articulate the criteria for success • Intended purpose

SWIFT - DO

Define the requirements	• Articulate the criteria for success
Describe the system	• Provide appropriate-level textual and graphical descriptions of the system or process to be risk assessed.
Identify the risks/hazards	• "**what-if**" technique is applied.
Assess the risks	• Estimate the risk associated with the identified hazards.

RECAP- FUNDAMENTAL QUESTIONS WHAT MIGHT GO WRONG? – HAZARD IDENTIFICATION

- What if material used is too concentrated (or diluted)?
- What if the valve/stopcock does not open (or close)?
- What if the valve(s) are opened (or closed) in the wrong sequence?
- What if inert gas is omitted?
- What if unintended materials are mixed together?
- What if readings are missed or ignored?
- What if warnings are missed or ignored?
- What if there are errors in diagnosis?

What If?	Answer	Likelihood	Severity	Recommendations
What could go wrong?	What would happen if it did?	How likely?	Consequences	What will we do about them Again – prevent and monitor
What if the inlet stream is blocked?				
What if the valve fails open / fails closed?				
What if an operator opens a wrong valve?				
What if the temperature transmitter stops working?				
What if the pipe leaks?				

Fundamental Questions:

1. What could go wrong?
2. What is the likelihood (probability) it will go wrong?
3. What are the consequences (severity)?

RISK ASSESSMENT MATRIX FOR SEVERITY AND

Risk Assessment Matrix for Severity and Occurrence	Severity	Catastrophic	Major	Moderate	Minor	Negligible
Occurrence		5	4	3	2	1
Almost Certain	5	25	20	15	10	5
Frequent	4	20	16	12	8	4
Occasional	3	15	12	9	6	3
Remote	2	10	8	6	4	2
Rare	1	5	4	3	2	1

Risk	Score	Action
Low	1 to 8	May be ignored, no further action or Ensure safe working
Medium	9 to 14	Monitor Control Measures
High	15 to 25	Error proof, Method /Design changes to address Failure modes

SWIFT - CHECK

Propose actions:

- Propose **risk control** action plans to reduce the identified risks to an acceptable level.

Review the process

- Determine whether the SWIFT met its objectives, or whether a more detailed risk assessment is required for some parts of the system

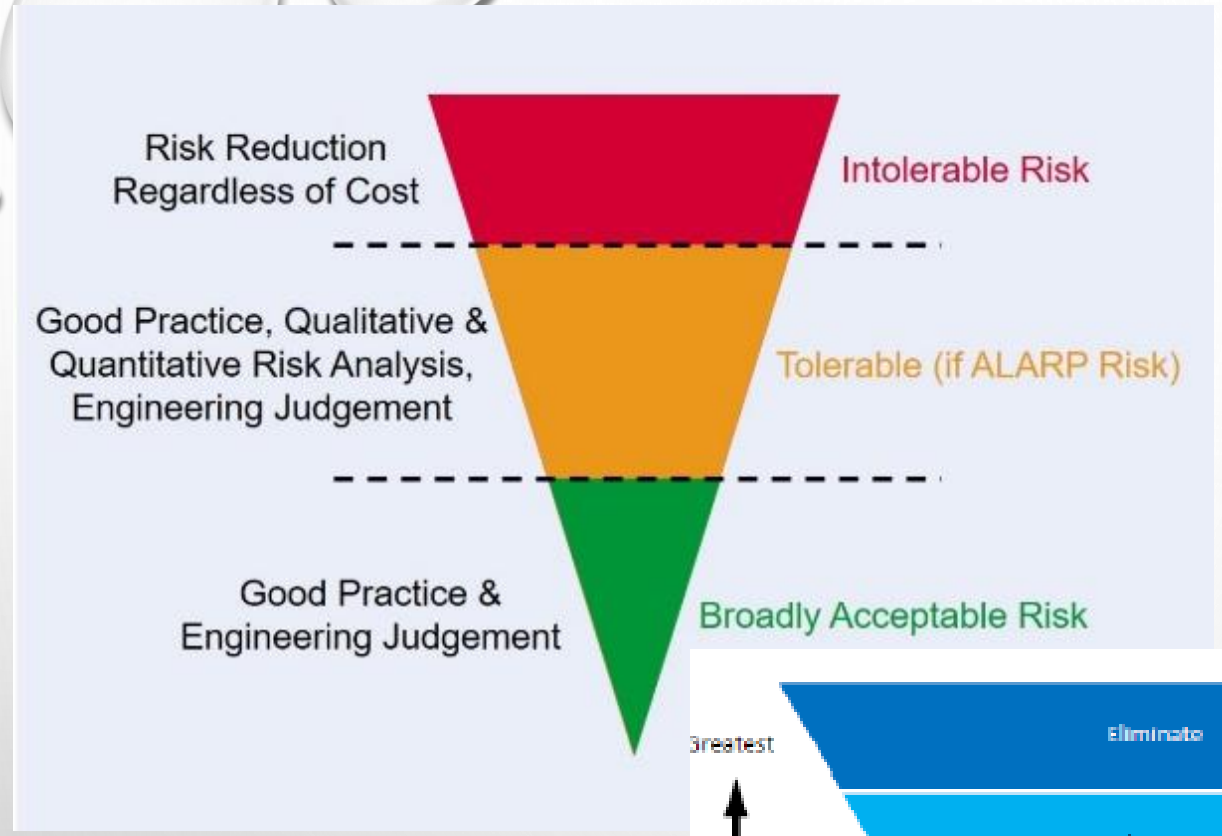
SWIFT - ACT

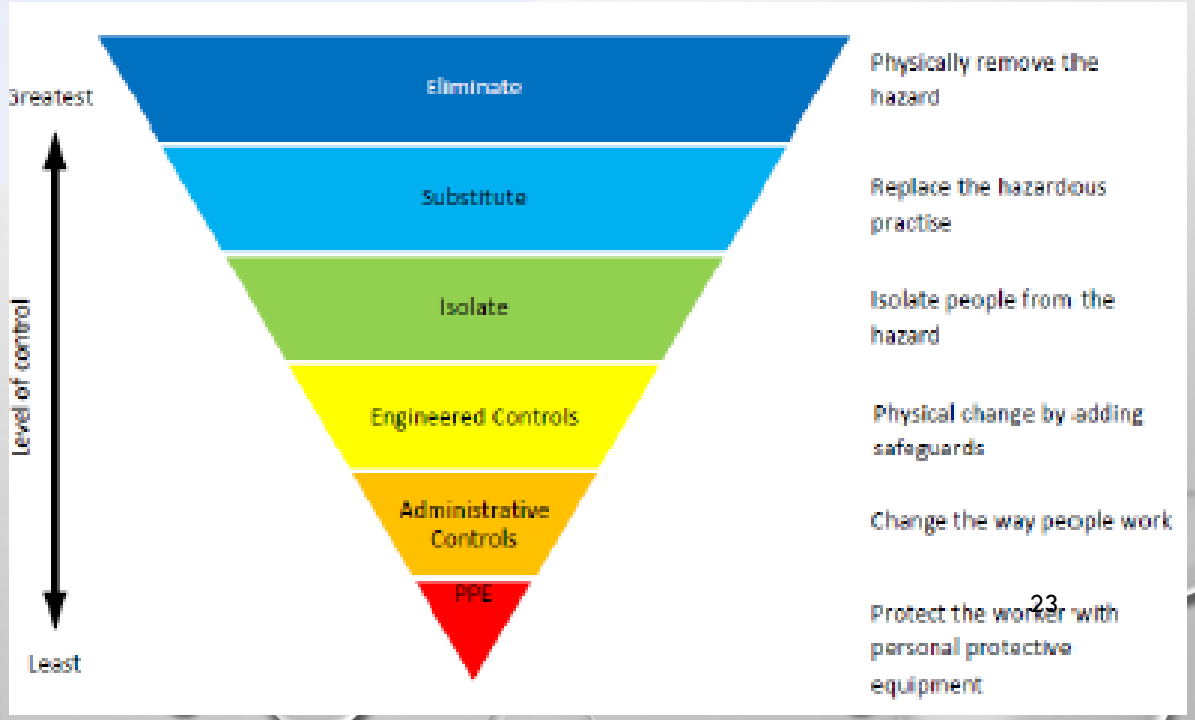
Document

- Produce an overview document to communicate the results

Additional risk assessment

- Conduct additional risk assessments using more detailed or quantitative techniques, if required.

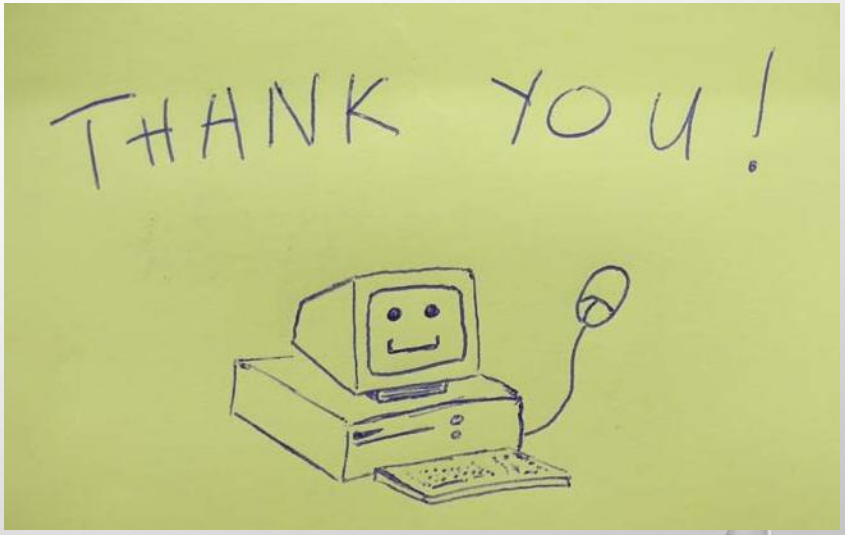

Risk Reduction
Regardless of Cost
Intolerable Risk
Good Practice, Qualitative &
Quantitative Risk Analysis,
Engineering Judgement
Tolerable (if ALARP Risk)
Good Practice &
Engineering Judgement
Broadly Acceptable Risk


Greatest
Level of control
Least
Eliminate
Substitute
Isolate
Engineered Controls
Administrative Controls
PPE
Physically remove the hazard
Replace the hazardous practise
Isolate people from the hazard
Physical change by adding safeguards
Change the way people work
Protect the worker with personal protective equipment

IDENTIFY RISK RESPONSES

- QUANTIFICATION OF RISK EXPOSURE OPTIONS AVAILABLE:
  - ACCEPT = MONITOR
  - AVOID = ELIMINATE *(GET OUT OF SITUATION)*
  - REDUCE = INSTITUTE CONTROLS
  - SHARE = PARTNER WITH SOMEONE *(E.G. INSURANCE)*
- RESIDUAL RISK *(UNMITIGATED RISK – E.G. SHRINKAGE)*


thanks a
minion


THANK YOU!