

Sneak Peek

Extractables and Leachables Control Strategies



Dr Mark Powell

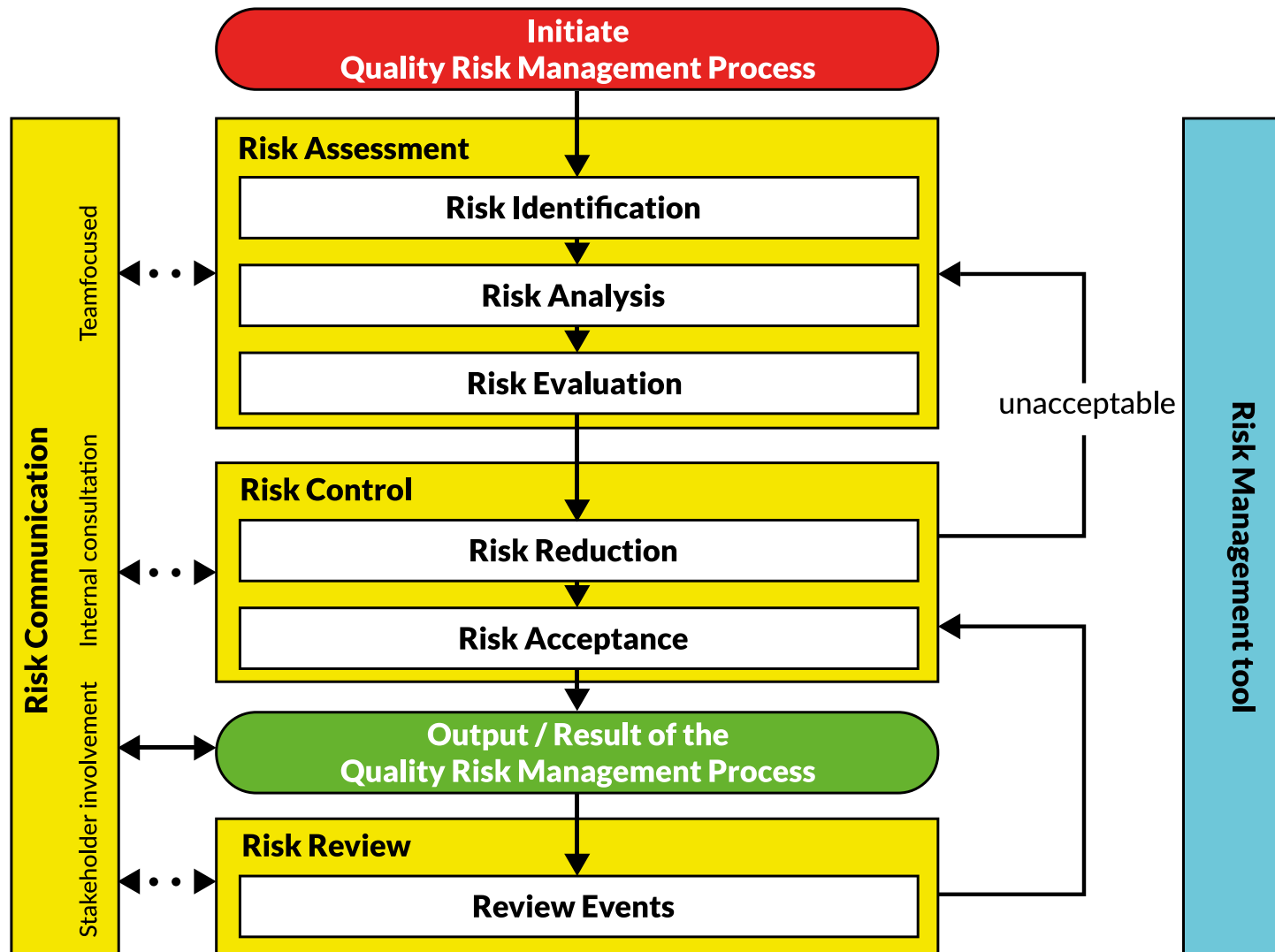
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SYMMETRIC

Risk Management Process

01

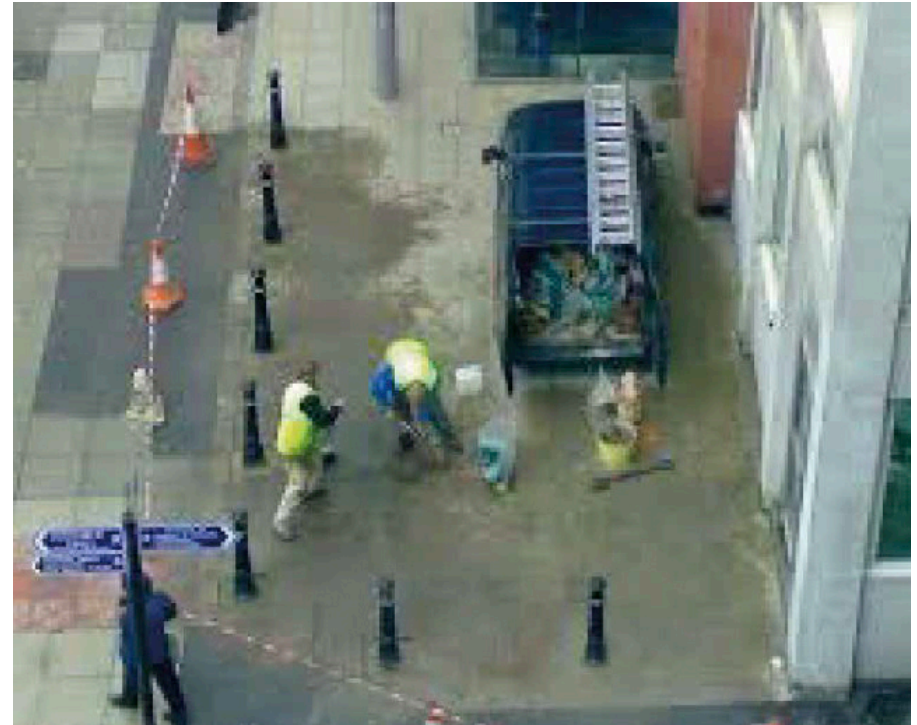


Risk Assessment



Consider:

- What might go wrong?
- What is the likelihood (probability) it will go wrong?
- What are the consequences (severity)?



Severity is often easier to assess
than likelihood

Risk Assessment Tools: FMEA



- FMEA (Failure Modes and Effects Analysis) is an analysis tool that helps to identify potential problems related to a product or process during their life cycle
- It addresses:
 - Potential failure modes
 - The effects of those failures
 - Prioritisation of failure modes for mitigation
- It is an important tool in risk management

When to use FMEA



- When a process:
 - Is being developed or changed
 - Is to be applied in a new way
 - Requires improvement
 - Is being investigated because of failures
- Before developing control strategies for new or modified processes
- Periodically throughout the life cycle of the process (continuous improvement)

When to use FMEA

05

- Assemble a cross-functional team with knowledge of the process, product or service
 - Brainstorming
 - Fishbone diagrams
- Define the scope of the FMEA
 - Use flowcharts to identify the scope and to make sure every team member understands it

Registration Sneak Peek

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