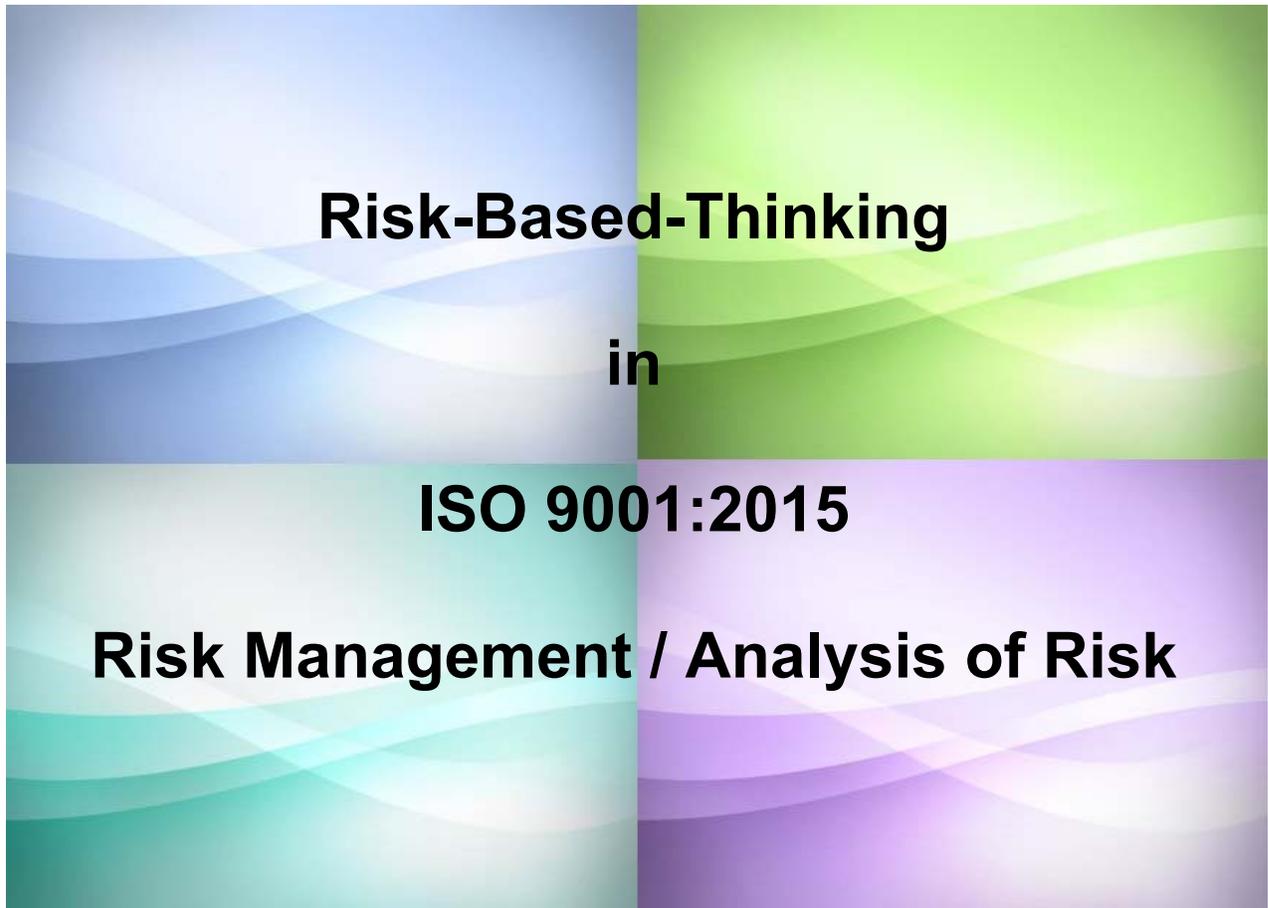


To fully address 'Risk' in IATF 16949:2016, a necessary start point is to consider the ISO 9001:2015 requirements associated with risk management and risk analysis.



The ISO 9001:2015 covers Risk in a number of sections (e.g. 4.4, 5.1, 6.1, 6.1.1, 6.1.2, 9.1.3, 9.3.2, & 10.2.1). The objective of the emphasis on risk is to have the organization, through its QMS, address uncertainty in processes that will affect the quality of the delivered goods or services to customers.

## **Risk Management**

The need to identify, analyze, and consider actual and potential risks was covered in various clauses of ISO/TS 16949:2009. The new IATF 16949:2016 standard continues to expect organizations to identify and address risks affecting compliance of products and services, resulting in improved customer satisfaction.

Besides identifying the risks, automotive organizations need to address opportunities for improvements, and corrective and preventive actions based on the risk analysis.

Note that in IATF 16949:2016 and while nonconformity and corrective action and preventive action are requirements at clauses 10.2, and 6.1.2.2 respectively, the concept of preventive action can be addressed through a risk-based approach where risks are determined and actions to address risks and opportunities are taken.

This risk analysis exercise is intended to outline several approaches / options for the management of risk at your company.

To prepare for the change, it is time to begin understanding Risk-Based Thinking and begin looking at your processes in terms of risks.

Risk is defined as the combination of the probability of occurrence of harm and the severity of that harm.

When evaluating risk, it is helpful to address it using two (2) metrics or parameters:

1. Severity (If harm happens, how serious is the event?)
2. Likelihood (What is the probability of a harmful event occurring?)

Because this topic is so important, it will have an impact on your QMS.

## **Risk-Based Thinking**

The risk management requirements are initiated in clause 6.1 of ISO 9001:2015. This clause addresses the risks and opportunities when planning for the quality management system. A more comprehensive IATF 16949:2016 introduces 'Risk-Based Thinking' in section 0.3.3 and expands on risk management in many sections of the standard.

### Clause 6.1 Actions to address risks and opportunities

- This clause addresses the risks and opportunities when planning for the quality management system.

#### Clause 6.1.2.1 Risk analysis

- At a minimum, this clause requires that companies include in their risk analysis, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework.
- Documented information be retained as evidence of the results of risk analysis.

IATF 16949 includes additional requirements for risk analysis in support of the continual need to analyze and respond to risk and to have suppliers and companies consider specific risks associated with the automotive industry where:

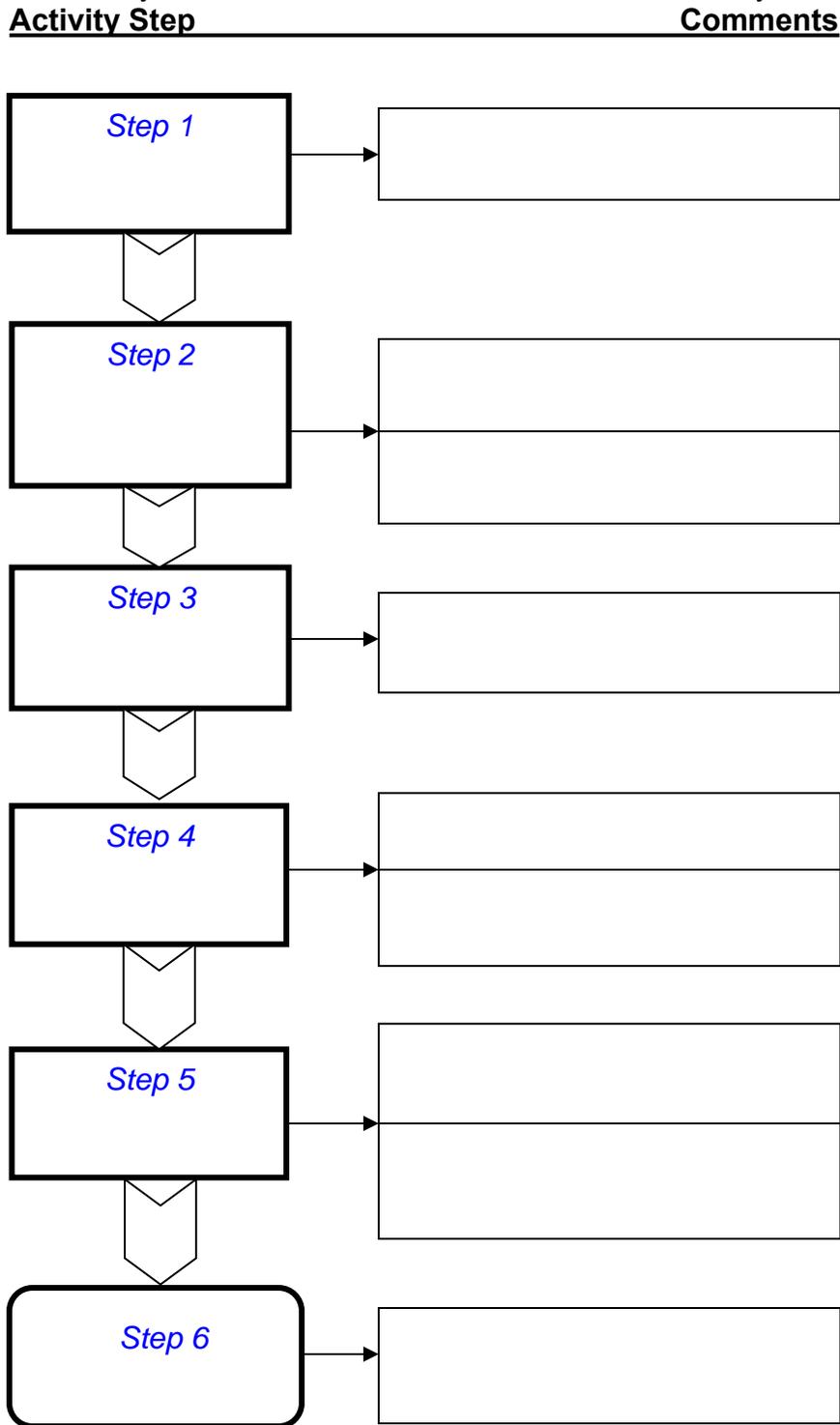
- Lessons learned are periodically reviewed and action plans implemented in response to these lessons.
- The effectiveness of the actions taken is evaluated and the actions integrated in the QMS.

Other risk management considerations deal with:

- Resources in Clause 7.1
- Competence in Clause 7.2
- Awareness in Clause 7.3
- Design and development in Clause 8.3
- Control of external providers in Clause 8.4

## Draw the Flow Diagram for the QMS Planning activities

**Example – Process for Planning of the QMS** - The Process Flow Diagram outlines each step of an activity or a function and includes relevant risk analysis comments for each step.

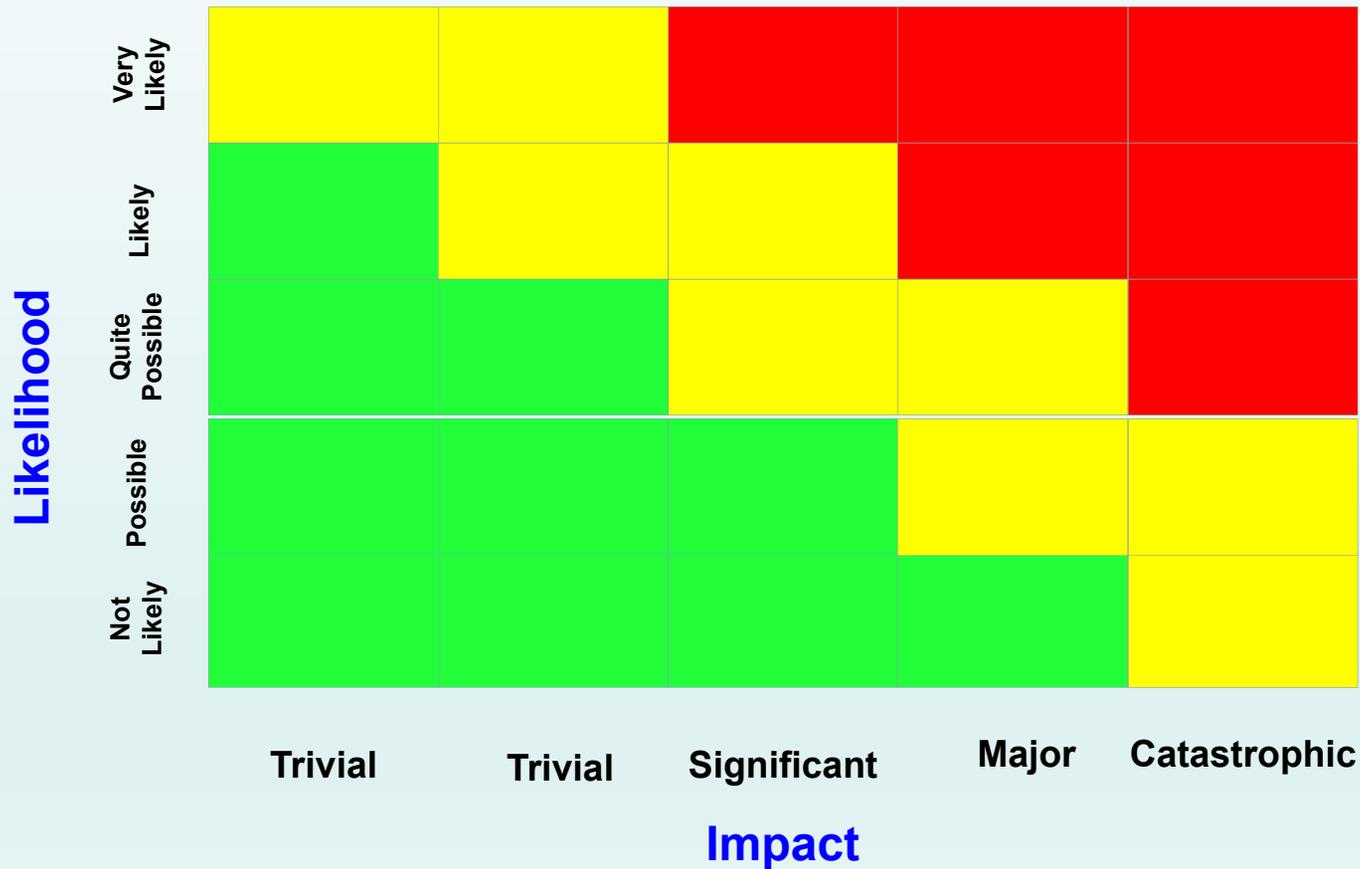


# **Risk Management / Risk Analysis in IATF 16949:2016**

**Committed to  
Continual  
Improvement**

# Risk-Based Thinking

An informal risk management system aimed at improvement



# Risk-Based Thinking

## Example: What can go wrong with a Process?

- Purchasing Process.
  - Single Source supplier is wiped out by Tsunami
- What is the impact?
  - You are shut down
- What is the likelihood it will happen?
  - Unlikely (But it happens)
- How do you mitigate the risk?
  - Find another supplier
  - Revise design to allow other options