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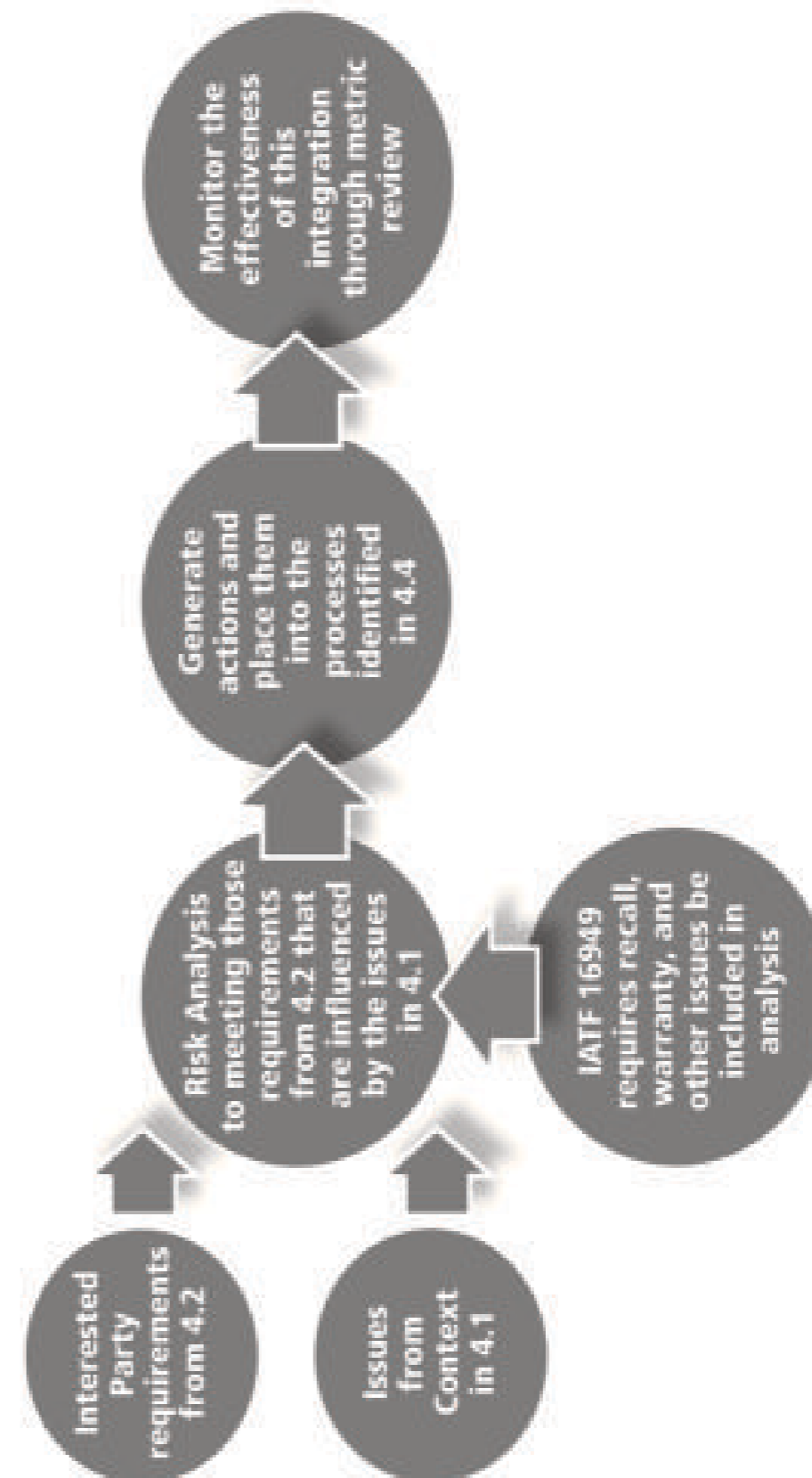
Refer to the chapter opening pages for detailed contents

Chapter SIX

PLANNING

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How to Integrate Risk into Process



6.1 Actions to Address Risks and Opportunities

6.1.2.1 Risk Analysis *Augmented*

The IATF 16949 standard **expands the inputs and the scope** of the information that must be considered when performing risk analysis. Because the automotive industry is such high volume the effect of product recalls on an organization's financial performance are often substantial. This is further aggravated by the fact that if a product is recalled the OEM bears the brunt of the customer dissatisfaction. The IATF 16949 standard requires the organization to expand their risk analysis to include these failures, because much like any other entity as the distance from the last major catastrophe grows, the memory of how we ended up there also tends to get fuzzy.

Internal items also need to be considered, such as scrap, because a high volume of NC parts can lead to short shipping or increasing the risk of sending NC material to the customer.

What is it?

- ▶ The risk assessment performed by an organization must include items such as product recalls and warranty returns as an input to the analysis
- ▶ This expanded data can be used to assess new risks for an existing requirement, or provide information on how severe it may be, or how often it may occur

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- ▶ **This analysis must be held as documented information** within the facility's QMS as part of its organizational knowledge
 - ▶ Inputs include both external sources as well as internal sources

How do I do it?

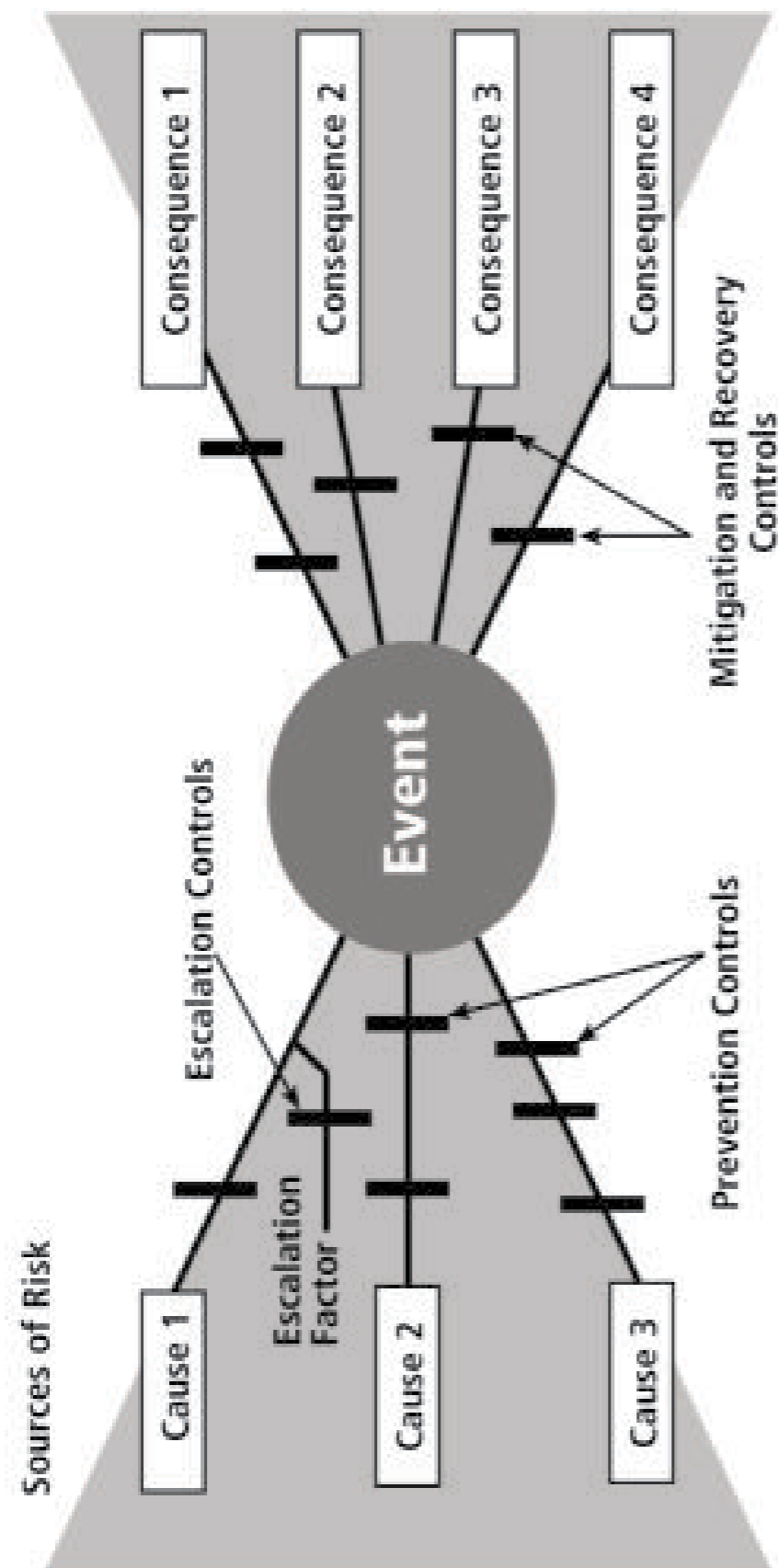


- ▶ Reach out to the areas of your organization that deal with warranty returns and field campaigns
- ▶ Identify areas in your facility where scrap data and other CoPQ (Cost of Poor Quality) data are collected
- ▶ Assess what portions of this data may result in:
 - A new potential risk to an objective
 - A source for the basis of **how severe** or **how likely** something may be
 - A source for how likely the occurrence of something may be
- ▶ Place this data into your organization's risk analysis making certain to identify the contributions of the various sources

Tools and Techniques to achieve it

- ▶ FMEA present in causes and ranking criteria (See the AIAG Core Tools manual for more information on Failure Mode and Effects Analysis)
- ▶ Bow Tie analysis

Bow Tie Analysis



- ▶ Risk mitigation template
- ▶ Any other quantitative risk assessment technique

For additional information refer to ISO 31000

Documents you can use to prove it



- ▶ A risk assessment template
- ▶ Warranty analysis reviews showing the information loaded into the risk analysis system as an input
- ▶ Turtle Diagram
- ▶ FMEA activities for existing products and processes including business processes (See the AIAG FMEA reference manual.)

Questions to ensure you know it

- ▶ How am I capturing the warranty and recall performance when I assess the risk of both my business and manufacturing operations?
- ▶ What would I show today if someone asked me to prove I added in the risks associated with the last field returns that I received?
- ▶ How do I use the production data from scrap and rework to tell how frequently something may happen...does it match what I think?
- ▶ What is the potential severity of a recall for my product, material, or service given my current traceability plan?