

Preventive Action through Risk-based Thinking

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ANSI National Accreditation Board

Key Takeaways

Understand risk-based thinking

Learn requirements for risk-based thinking

Use risk-based thinking as a preventive action process

Determine how risk-based thinking can enhance opportunities



Why this Topic?

Risk-based thinking replaces traditional preventive action requirements

- Encourage organizations to use risk-based thinking as ongoing activity to prevent nonconformities from occurring

Requirements for addressing risks and opportunities incorporated into management system requirements

- Risk-based thinking should be embedded throughout technical requirements



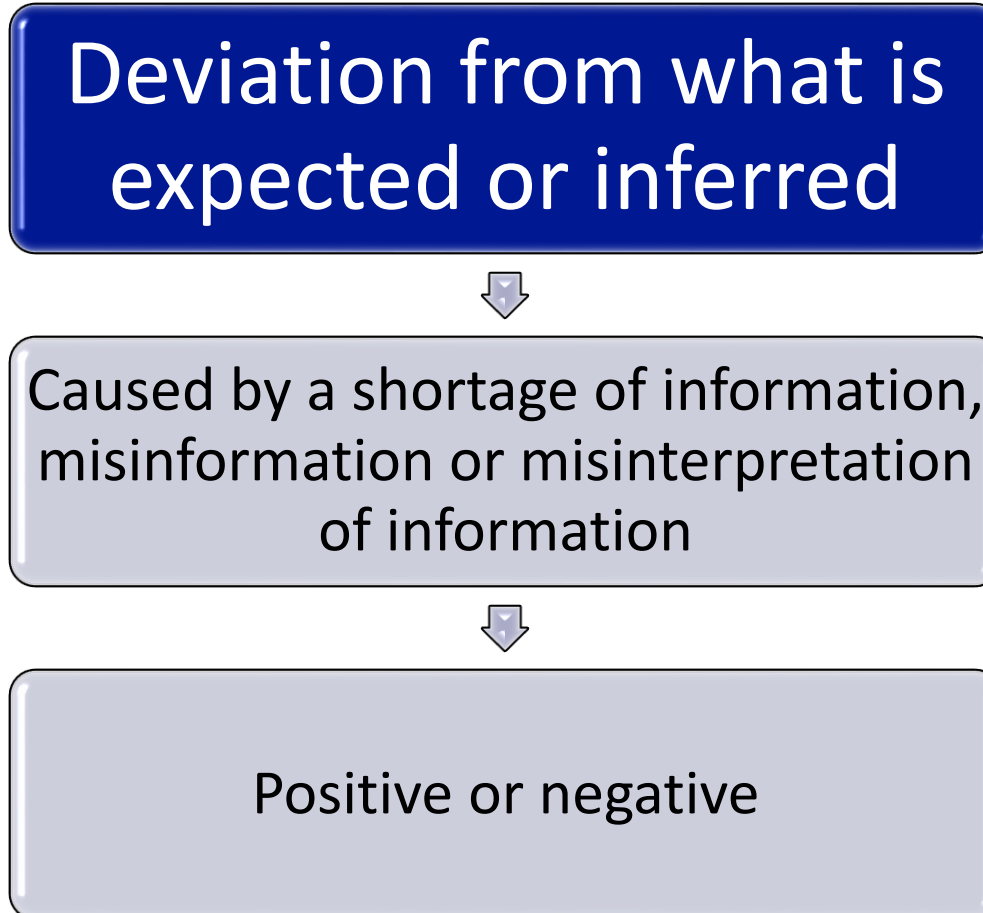
What is Risk?

Effect of
uncertainty

[ISO 9000:2015, 3.7.9]

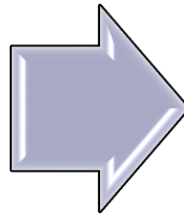


What is Risk?



What is Risk-based Thinking?

Consideration of
potential events,
consequences and
likelihood of occurrence



Aim to prevent potential
negative events from
occurring



What is Preventive Action?

Action to eliminate
the cause of a
potential
nonconformity

Action taken to
prevent
occurrence



Why Shift from Preventive Action to Risk-based Thinking?

Preventive action

- Often forgotten process
- Not effective in continuous improvement

Risk-based thinking

- Integrated into management system
- Proactive approach to preventive action



Continuous Improvement

Embedded in culture of organization

- Consideration of risks and opportunities in all processes

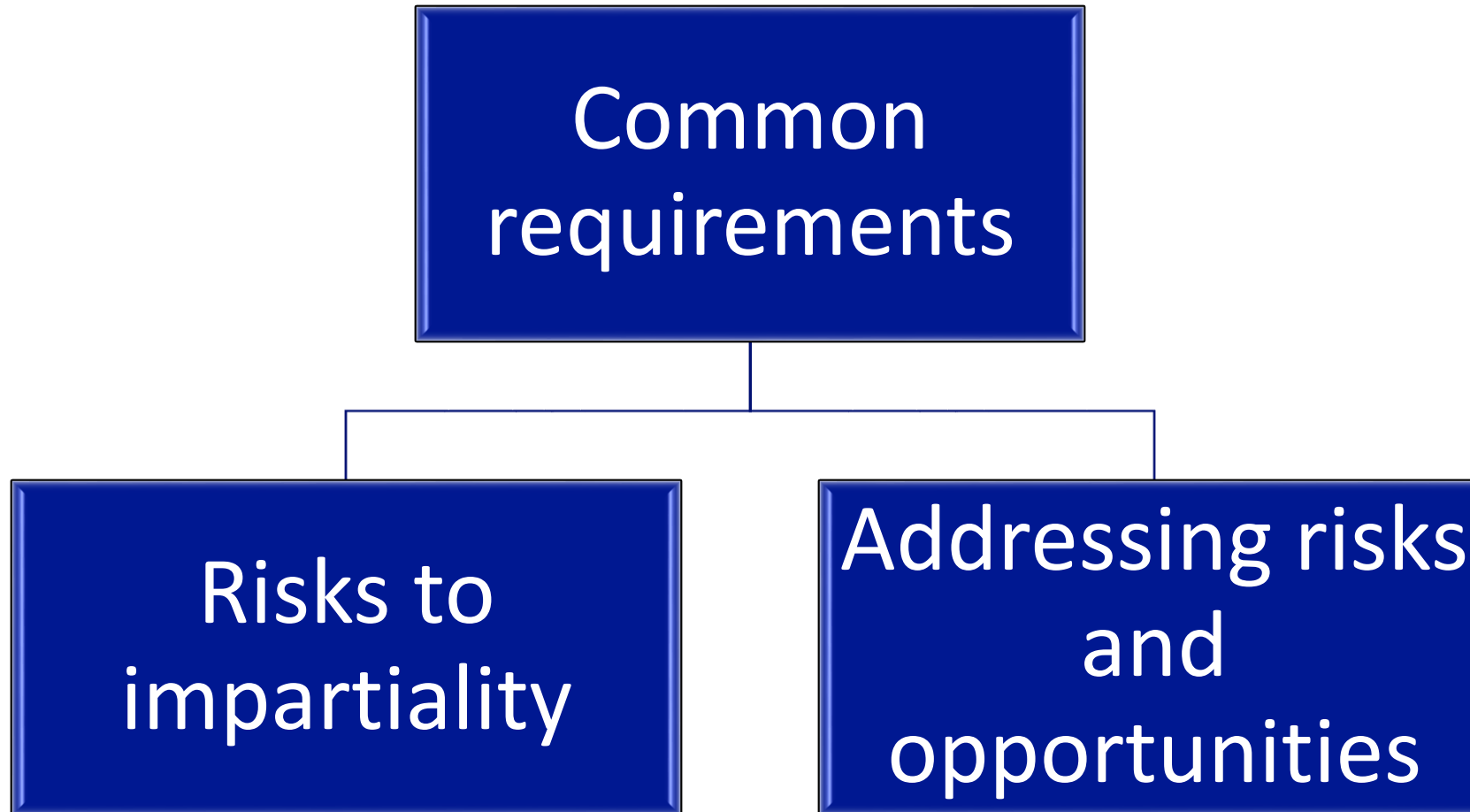
Tied to organizational objectives



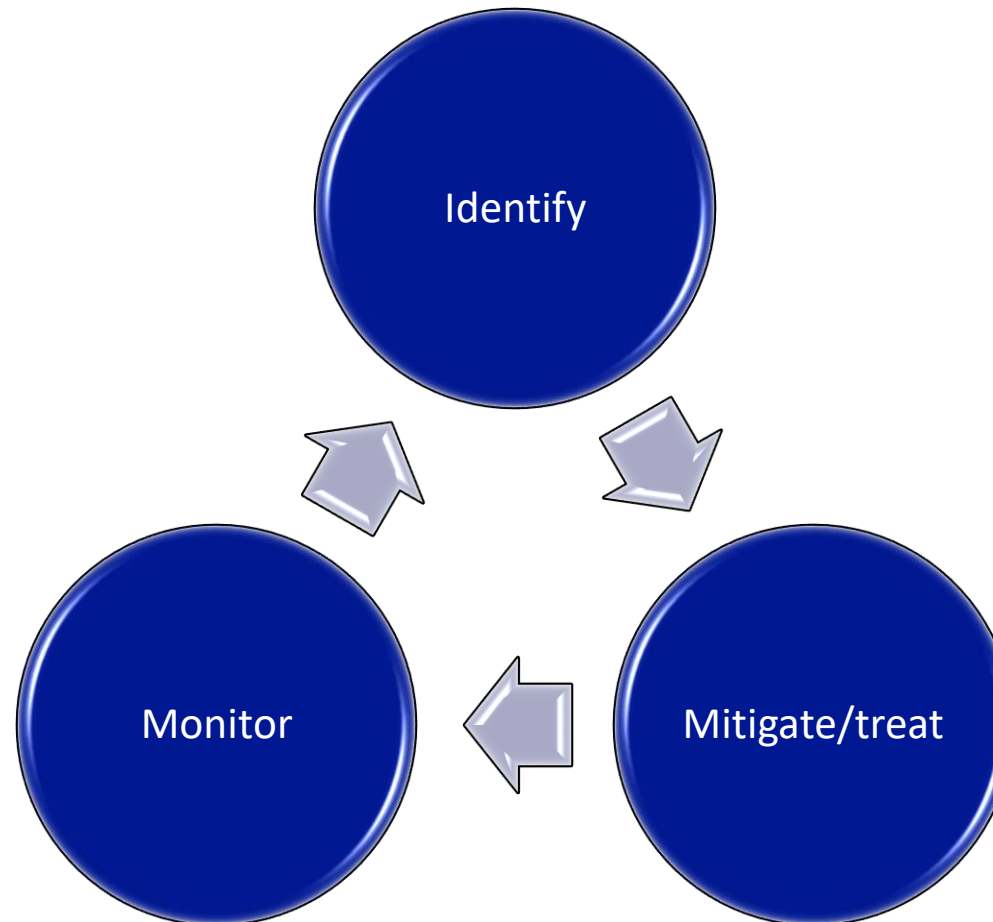
What is Needed for Risk-based Thinking?



Standard Requirements for Risk-based Thinking



Proactive Approach



Sources of Risk Identification

Contract review

Internal audits

Complaints

Corrective
actions

Nonconforming
work

Management
review



Evaluating Consequences

Impact analysis

Trivial

Minor

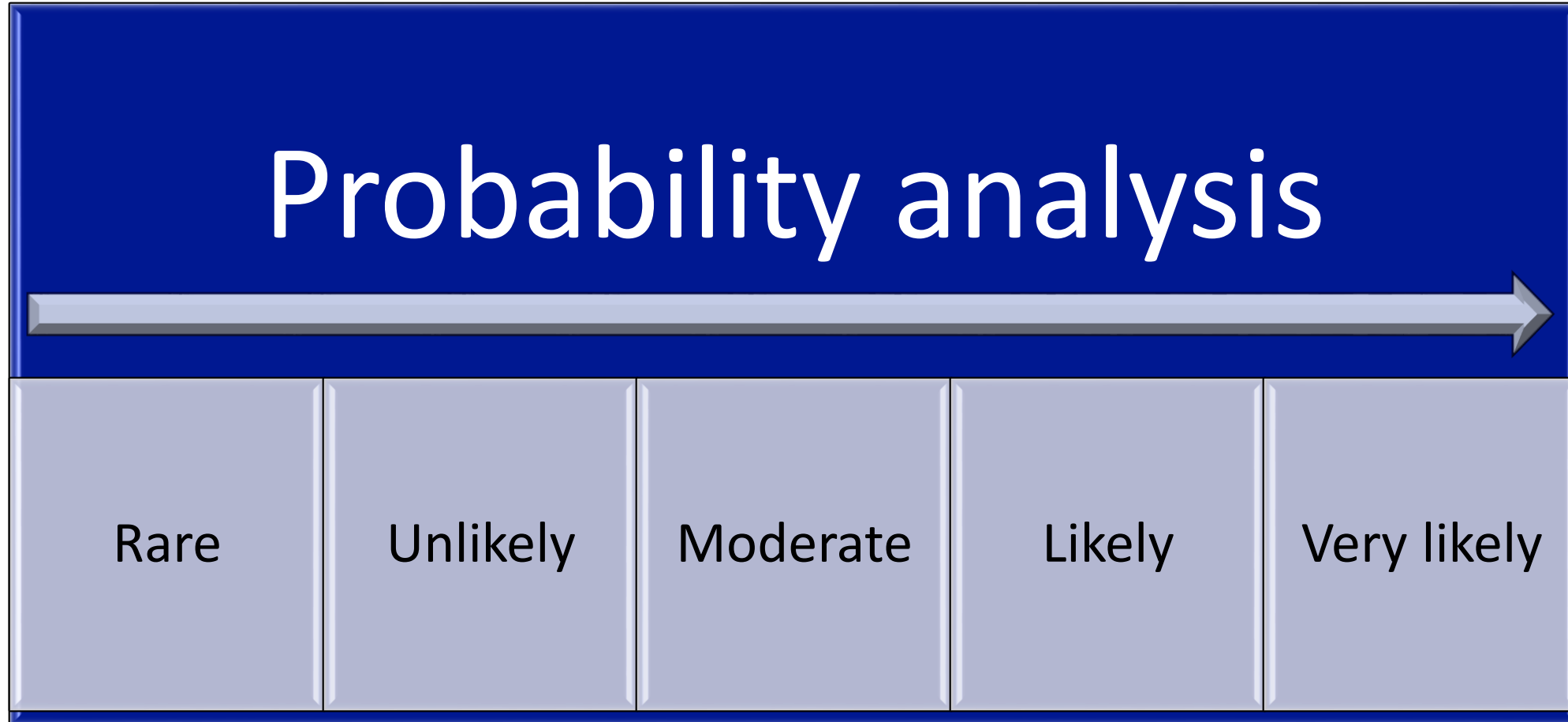
Moderate

Major

Extreme



Evaluating Likelihood



Simple Risk Analysis Process



Risk-based Thinking as Preventive Action

Eliminate potential risks through preventive actions

- Change processes
- Train personnel
- Obtain resources

Reduce consequence or impact

Reduce likelihood or probability



What is an Opportunity?

Risk occurrence that would have a favorable impact

A condition or state with the potential to lead to a benefit or gain

Potential beneficial effects

Situation from which an organization can derive benefit

A risk that would have a positive effect on one or more objectives



Risk-based Thinking and Opportunities

Expand business
operations

Obtain new
customers

Gain insight into
internal and
external issues

Future-thinking
and planning



Conclusions

Risk-
based
thinking
is

- Embedded in organizational operations
- Tied to organizational objectives
- Proactive approach to preventive action
- Useful to mitigate risk and enhance opportunities



Contact Information

For additional
information related to
training, contact

training@anab.org

For additional
information related to
accreditation services,
contact

anab@anab.org

anab.ansi.org

