Risk Assessment and Management

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Standard Disclaimer

Standard Disclaimer:

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Overview

- Concepts
- Definitions
- Specific Applications

What is Risk

Risk and Consequences

Definitions

Hazard:

- The potential source of harm (ISO/IEC Guide 51)

Risk:

- The combination of the probability of occurrence of harm, and the severity of that harm (ISO/IEC Guide 51)

Quality:

- The degree to which a set of inherent properties of a product, system, or process fulfills requirements. (ICH Q9)

Definitions

Risk Acceptence:

- The decision to accept risk (ISO Guide 73)

Risk Analysis:

- The estimation of the risk associated with the identified hazards (ICH Q9)

Risk Assessment:

- A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of the hazards, and the analysis and evaluation of risks associated with the exposure to these hazards (ICH O9)

Definitions

Risk Communication:

- The sharing of information about risk and risk management between the decision maker and the stakeholder

Risk evaluation:

- The comparison of the estimated risk to given risk criteria using a quantitative or qualitative scale to determine the significance of the risk

Risk identification:

- The systematic use of informaton to identify potential sources of harm (hazards) referring to the risk question or problem description.

Definitions

Risk management:

- **The systematic application of quality management policies, procedures and practices to the tasks of assessing, controlling, communicating, and reviewing risk.**

Risk reduction:

- **Actions taken to lessen the probability of occurrence of harm and the severity of that harm.**

Risk review:

- **Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.**

Definitions

Severity:

- **A measure of the possible consequences of a hazard**

Stakeholder:

- **Any individual, group, or organization that can affect, be affected by, or perceive itself to be affected by a risk. Decision makers might also be stakeholders.**

Hazard

- A real or potential condition, situation, or agent that could cause immediate or long-term harm to people or an organization; damage or loss of a system, equipment, property, or the environment, or other things of value

James L. Vesper

Risk Assessment and Risk Management in the Pharmaceutical Industry (2006) PDA/DHI

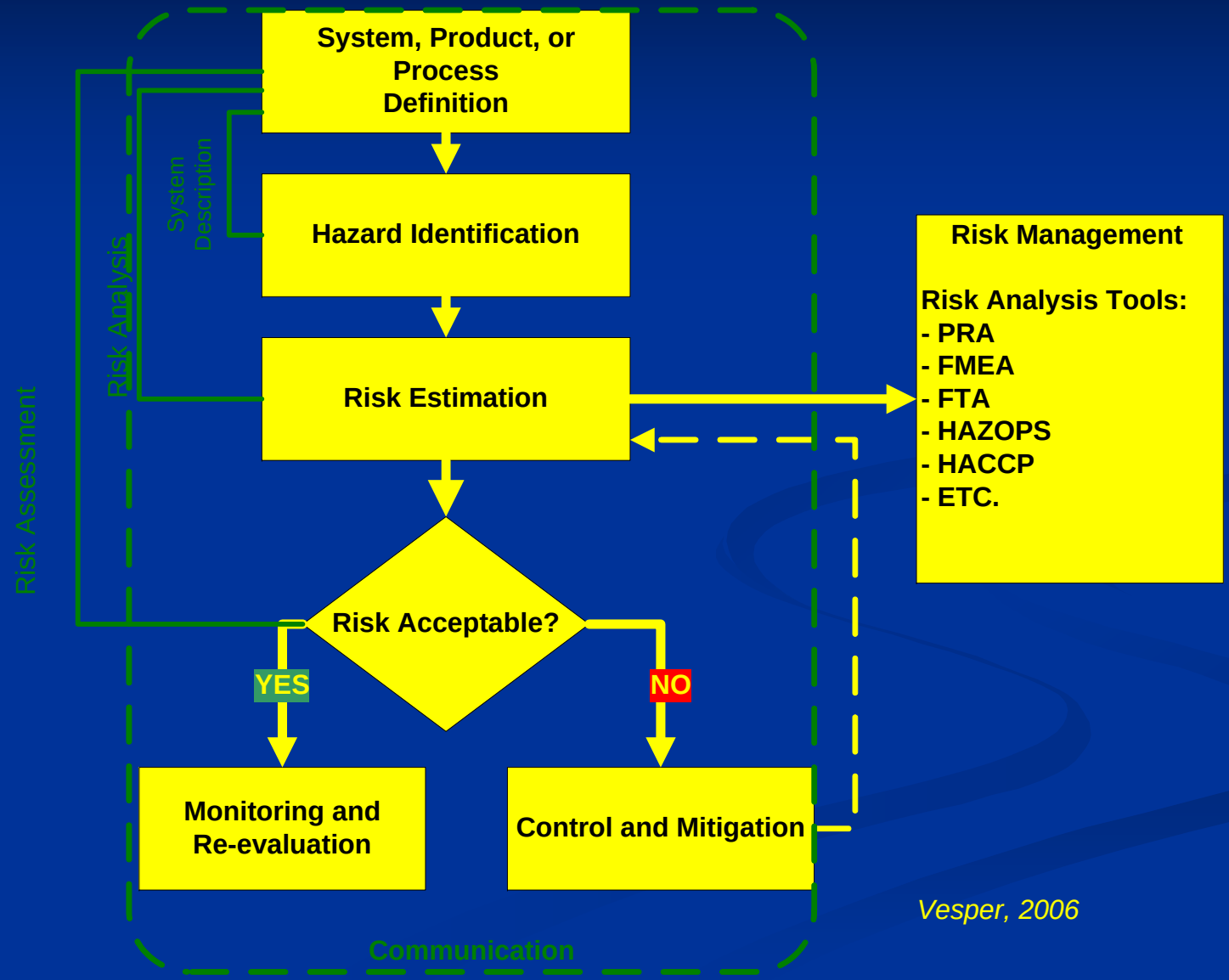
Risk

- Risk is the possibility that human activities or natural events will lead to consequences that affect what people value. It is a measure of the potential ability to achieve overall program objectives within defined costs, schedule, and performance criteria. Risk has three components:
  - What could go wrong?
  - What is the *probability* of failing to achieve a particular outcome?
  - What is the *impact* of failing to achieve a particular outcome?

The Risk Management Process

- System Definition
- Hazard Identification
- Risk Estimation
- Risk Evaluation
- Risk Control
- Risk Monitoring and Re-evaluation
- Risk Communication

The Risk Management Process



Vesper, 2006

Risk Management Process

- Establish overall structure, goals
- Establish team
- Define the scope for the process/product
- Identify the potential hazards
- Identify how risk can be expressed and criticality
- Determine if the risk is acceptable
- If risk is to be controlled, identify appropriate methods

Risk Management Process

- Re-evaluate the controlled risk to determine if risk is now acceptable
- Implement risk control methods
- Compile records to document activities
- Monitor the process for effectiveness
- Actively communicate with stakeholders throughout the process!

System Definition

- What is to be evaluated?
- What stage of production is being evaluated?
- Why is this being evaluated?

- Assemble cross-functional team for assessment

Hazard Identification

- Is there an intrinsic hazard?
- Are there multiple hazards?
- Are the hazards immediately detectable, or are they long-term?
- Does the hazard trigger a chain reaction of events?
- Who or what do the hazards effect?

Risk Estimation

- What is the probability that the risk is expressed?
  - Qualitative
  - Semi-quantitative
  - Quantitative
- What is the impact of the resulting effects?
  - Local effects
  - End effects

Risk Evaluation

- Is the risk acceptable?
- Do the risks need to be mitigated or controlled?
- ALARA – As Low As Reasonably Achievable
- ALARP – As low As Reasonably Practicable

Risk Control

- How can the risk be controlled?
  - Substitution
  - Uncoupling
  - Process simplification
  - Isolation
  - Elimination
  - Changing conditions
  - Providing more information

Risk Control

- How can the risk be controlled?
  - Decreasing the frequency of an event happening
  - Decreasing the consequences
  - Duplicating assets
  - Changing the source
  - Implementing standard procedures
  - Engineering controls
  - Training and preparedness

Risk Monitoring and Re-evaluation

- Collect data on the process
- Have any unpredicted risks appeared?
- Risk environment changes
  - Company expectations
  - Regulatory environment
  - Societal expectations

Risk Communication

- Effective communication should take place throughout the entire risk management process.
- Include ALL stakeholders!

Risk Assessment Tools

- **FMEA and FMECA**
- Fault Tree Analysis
- Event Tree Analysis
- Hazard Operability Studies
- **HACCP**
- Preliminary Risk Analysis
- etc.

FMEA and FMECA

- Failure Mode Effects Analysis
- Failure Mode Effects & Criticality Analysis
  - Adds criticality analysis to FMEA
- Structured inductive tools to identify known or potential failure modes

FMEA and FMECA

- Benefits:
  - Used to examine high-level systems or small components
  - Scalable
  - Quantitative or semi-quantitative
- Limitations
  - Each event is a separate occurrence
  - Does not show interactions

FMEA and FMECA

1. Define what is being analyzed
2. Identify the potential failure modes
3. Identify the effects of each failure mode
4. Rate each effect for:
   - Probability of occurrence
   - Severity
   - Detectability
   - Calculate Risk Priority Number
     - RPN = probability x severity x detectability*

FMEA and FMECA

5. Prioritize the effects based on RPN and determine risk acceptability
6. If risk acceptable, continue monitoring
7. If risk must be modified or eliminated, consider appropriate control or mitigation strategies
8. Prepare report and retain documentation

The PROBABILITY of Occurrence

Probability Rating	Amount of Data	Probability of Occurrence of Adverse Event
1	significant data on the same activity	virtually no likelihood
2	significant data on similar activities	very low likelihood
3	limited data on similar activities	low likelihood
4	significant data on similar activities	fair likelihood
5	limited data on similar activities	fair likelihood
6	significant data on dissimilar activities	fair likelihood
7	limited data on dissimilar activities	good likelihood
8	no prior data on similar activities	good likelihood
9	limited prior data on similar activities	significant likelihood
10	significant data on similar activities	near certain

IMPACT OF RISK ON THE PERFORMANCE OF THE PRODUCT OR SERVICE

Impact Rating	Product or Service Quality Impact	Process Changes
1	no measurable impact	none
2	some negative impact	remains well within acceptable tolerances
3	some negative impact	remains within acceptable tolerances
4	impact negatively	requires very minor changes in production
5	impact negatively	requires modest changes in production
6	significant, negative impact	requires work-arounds to meet acceptable tolerances
7	significant, negative impact	extensive work-arounds may be necessary
8	significant, negative impact	extensive work-arounds are necessary
9	critically negative impact	even the work-arounds present significant risk
10	critically negative impact	there is no alternative or solution

Impact and Probability The Severity Index

Probability		Severity									
	10	10	20	30	40	50	60	70	80	90	100
	9	9	18	27	36	45	54	63	72	81	90
	8	8	16	24	32	40	48	56	64	72	80
	7	7	14	21	28	35	42	48	56	63	70
	6	6	12	18	24	30	36	42	48	54	60
	5	5	10	15	20	25	30	35	40	45	50
	4	4	8	12	16	20	24	28	32	36	40
	3	3	6	9	12	15	18	21	24	27	30
	2	2	4	6	8	10	12	14	16	18	20
	1	1	2	3	4	5	6	7	8	9	10
		1	2	3	4	5	6	7	8	9	10

Highest Impact of the Risk Event

Risk Level	Definition
High 60 & above	Because concerted and continual emphasis and coordination may not be sufficient to overcome major difficulties, these events must be placed in the program and fully funded. They are likely to cause significant disruption in the schedule, increase in cost (relative to the total production cost of the product), and/or degradation of technical performance.
Medium 20 - 59	Special emphasis and close coordination will be required to mitigate this risk. Should this risk occur significant disruption of schedule, increase in cost (relative to the production cost of the product) and/or degradation of technical performance is likely.
Low Below 20	Normal emphasis and close coordination should be sufficient to mitigate major difficulties. However, should this risk occur, there is potential for disruption of schedule, increase in cost (relative to the production cost of the product), and/or degradation of technical performance. Fund at the risk-adjusted value.

Risk in Project Management

When *everything* is a priority,

nothing is a priority!

The PROBABILITY of Occurrence

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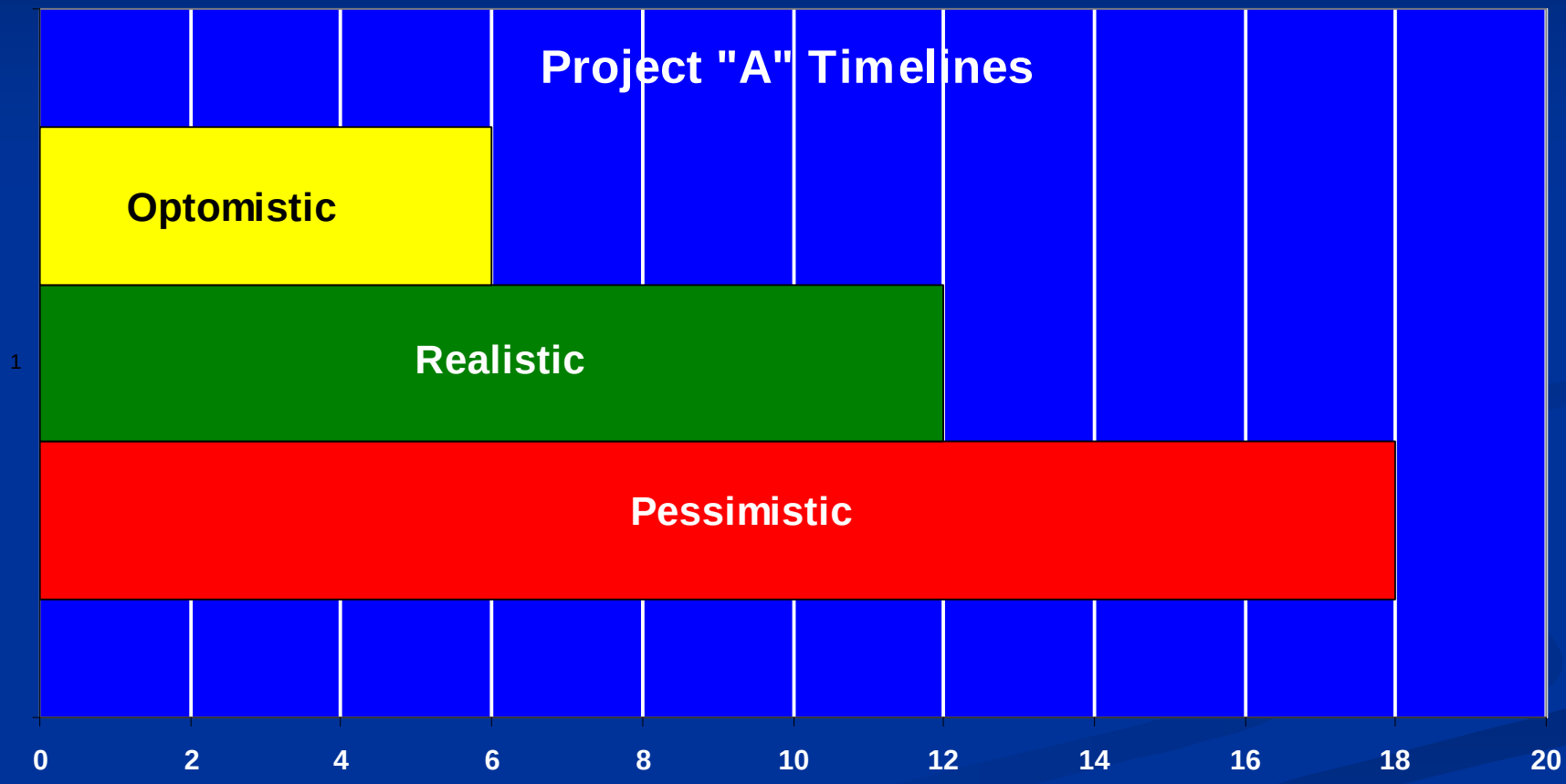
10	significant data on similar activities	near certain

IMPACT ON THE ACTIVITY SCHEDULE SHOULD A RISK EVENT OCCUR

1. A risk event occurs, and has a small, immeasurable impact on the activity under assessment.
2. A risk event occurs, and the time to complete the activity under assessment has been extended by 1 month.
3. A risk event occurs, extending the activity schedule by 2 to 3 months.
4. A risk event occurs, extending the activity schedule by 3 to 6 months.
5. A risk event occurs and extends the activity schedule by 6 to 9 months.
6. A risk event occurs and extends the activity schedule by 9 to 12 months.
7. A risk event occurs and extends the activity schedule by 12 to 18 months.
8. A risk event occurs and extends the activity schedule by 18 to 24 months.
9. A risk event occurs and delays the activity schedule by more than two years.
10. A risk event occurs and it stops the program!

Risk Effects on Timelines



HACCP

- Hazard Analysis and Critical Control Points
- Originally established for use in the food industry
- A system of hazard control pioneered by the Pillsbury Co.
- Now accepted internationally as a system of food risk assessment.
- Can easily be adapted to other industries

HACCP Preliminary Activities

1. Assemble the HACCP team
2. Describe the product and its distribution
3. Describe the intended use and consumers of the product
4. Develop a process flow diagram
5. Verify the flow diagram

HACCP Principles

1. Conduct a Hazard Analysis
2. Identify the Critical Control Points in the Process
3. Establish critical limits associated with each identified control point
4. Establish CCP monitoring requirements

HACCP Principles

5. Establish corrective action when deviation occurs
6. Establish effective recordkeeping to document HACCP system
7. Establish procedures to verify HACCP system is working
8. Establish procedures to verify HACCP system is working

Conduct a Hazard Analysis

- Team uses the process flow diagram to identify any risks that may occur at a given process step.
- Assess the risks for probability of occurrence and impact
- Assess potential preventative measures

Identify the Critical Control Points in the Process

- A critical Control Point is a step or procedure that can be applied, and a food hazard prevented, eliminated, or reduced to an acceptable level.
- Example: a specified heat process, at a given time and temperature to destroy a specified microbial pathogen, is a CCP.

Establish Critical Limits Associated With Each Identified Control Point

- A critical limit is defined as a criterion that must be met for each preventative measure associated with a CCP.
- Each CCP may have one or more preventative measures for the CCP

Establish CCP Monitoring Requirements

- Monitoring is a planned sequence of observations to assess if a CCP is under control, and produce an accurate record.
- If monitoring shows the process to begin to lose control, the process can be modified to bring it into control.

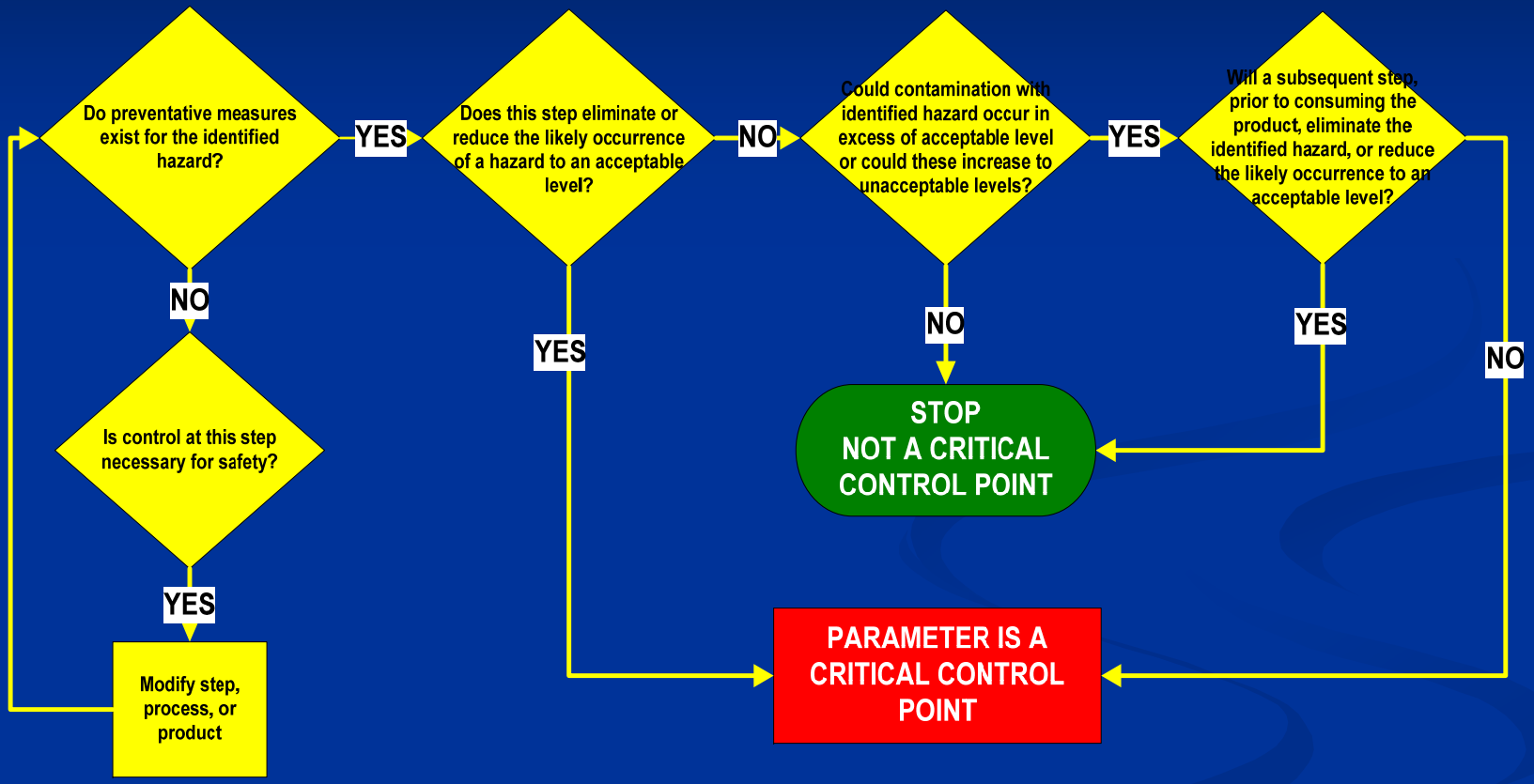
Establish Corrective Action When Deviation Occurs

- Develop a plan to:
  - Dispose of non-compliant product
  - fix or correct the cause of the deviation
  - maintain records documenting the corrective actions
- The data must demonstrate that the CCP can be brought into control

Establish Effective Recordkeeping To Document HACCP System

- The HACCP records should:
  - List the HACCP team and responsibilities
  - Describe the product and intended use
  - Contain a flow diagram indicating the CCPs
  - Identify hazards associated with each CCP and preventative measures
  - Critical limits
  - Describe the monitoring system
  - Describe corrective action plans
  - Describe recordkeeping procedures
  - Describe procedures for verification of HACCP system

HACCP Flowchart



Risk and Consequences

Risk and Consequences

"Red on yellow, kill a fellow. Red on black, won't hurt Jack."

For Additional Information

- Vesper, James Risk Assessment and Risk Management in the Pharmaceutical Industry Clear and Simple. 2006. PDA/DHI
- ICH Q9 Quality Risk Management (2006) U.S. Food & Drug Administration.
- HACCP: Establishing Hazard Analysis Critical Control Point Programs (1993) Food Processors Institute
- ISO/IEC Guide 73:2002 – Risk Management – Vocabulary-Guidelines for use in standards
- Stamatis, D.H. Failure Mode and Effect Analysis (1995) ASQ Quality Press

Thank You!