



# How Do I

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## Perform Risk Minimization/ Mitigation/Reduction

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## Steps To Risk Management

Risk Management is a continuous cycle composed of:

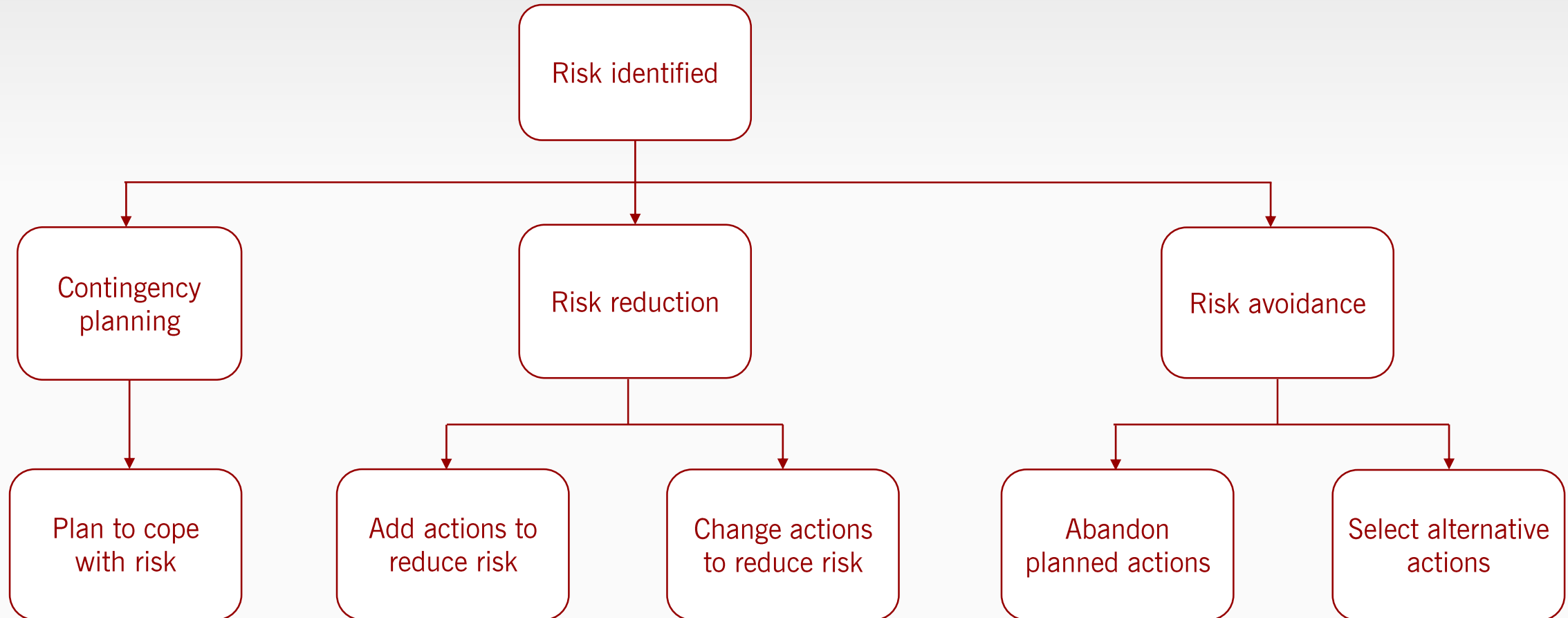
- Risk Assessment (See Part 1)
- Risk Minimization/Mitigation/Reduction

# Review of Risk Management Process

## Risk Assessment:

- Analysis that identifies critical control points in software where, if there is a failure or malfunction, harm to a patient, donor or business may occur
- Tools that allow validation resources to focus on critical areas of an automated system

# Risk Management



## Three Steps To Determine Levels Of Risk

1. Identify risks and create a Risk Document
2. Apply empirical techniques to analyze the situation in terms of consequences and likelihood
3. Estimate likelihood/consequences and develop mechanism to apply category

## What is the Goal of Risk Minimization?

- Objective is to minimize a product's risks to an acceptable level while preserving the benefits

## Risk Minimization

- Develop Strategies and Controls to Eliminate/Reduce/Mitigate
- Select/Implement Strategy
- Assure Effectiveness
- Assure No New Risks Created
- Warnings
- Workarounds

# What Are Some Mechanisms of Risk Minimization?

- Design Controls
  - Change System Programmatically-Vendor Needed
  - Change System using Configuration Change
  - Warnings
- Documentation Control
  - New SOP with work-around for the risk identified to ensure that no one will be effected by risk



# Example 1: Procedural Workarounds

## **Requirement:**

L6.0: The system shall allow the user to add unit attributes [CMV Neg, Irradiated, etc.]

## **Unsatisfactory Outcome:**

If a product is modified by a defined modification procedure and then special testing is added to the parent product in the Correct Inventory-Special Testing tab, the system does not transfer this information to any existing children units. Vice versa, if special testing is added to an existing child unit this information is not added to the parent unit

## **Mitigation/Workaround:**

If special testing needs to be added to a product record after a modification procedure has been performed, the user will need to add this special testing to all products (the original parent and children units) that exist for the entered product number. This change customarily takes the least amount of time to implement.

# Example 2: Changes to Configuration (Control Settings)



## **Requirement:**

N2.26: The system shall capture all overrides performed during the issue process and send them to the exception report

## **Unsatisfactory Outcome :**

The system allows a user to dispense a red blood cell product with an incompatible crossmatch with no system generated warning. The user is unaware that a unit with an incompatible crossmatch is being dispensed.

## **Mitigation/Workaround:**

It is recommended that the client make changes to appropriate Control Settings in the Computer system if possible so that the system DOES warn when the user when a red blood cell product with an incompatible crossmatch is dispensed.

This usually involves, not only Training (PQ) of end users, but also Testing and Validation (IQ, OQ,) of the changes and any other functionality related to the Configuration. The PLUS side of this type of change is that you can control the timing, since the Administrator of the system can control access for changes as such.

# Example 3: Changes to Computer Software



## **Requirement:**

N1.17: The system shall have the ability to display a warning message if a user selects a product that was previously resulted as incompatible for the same patient

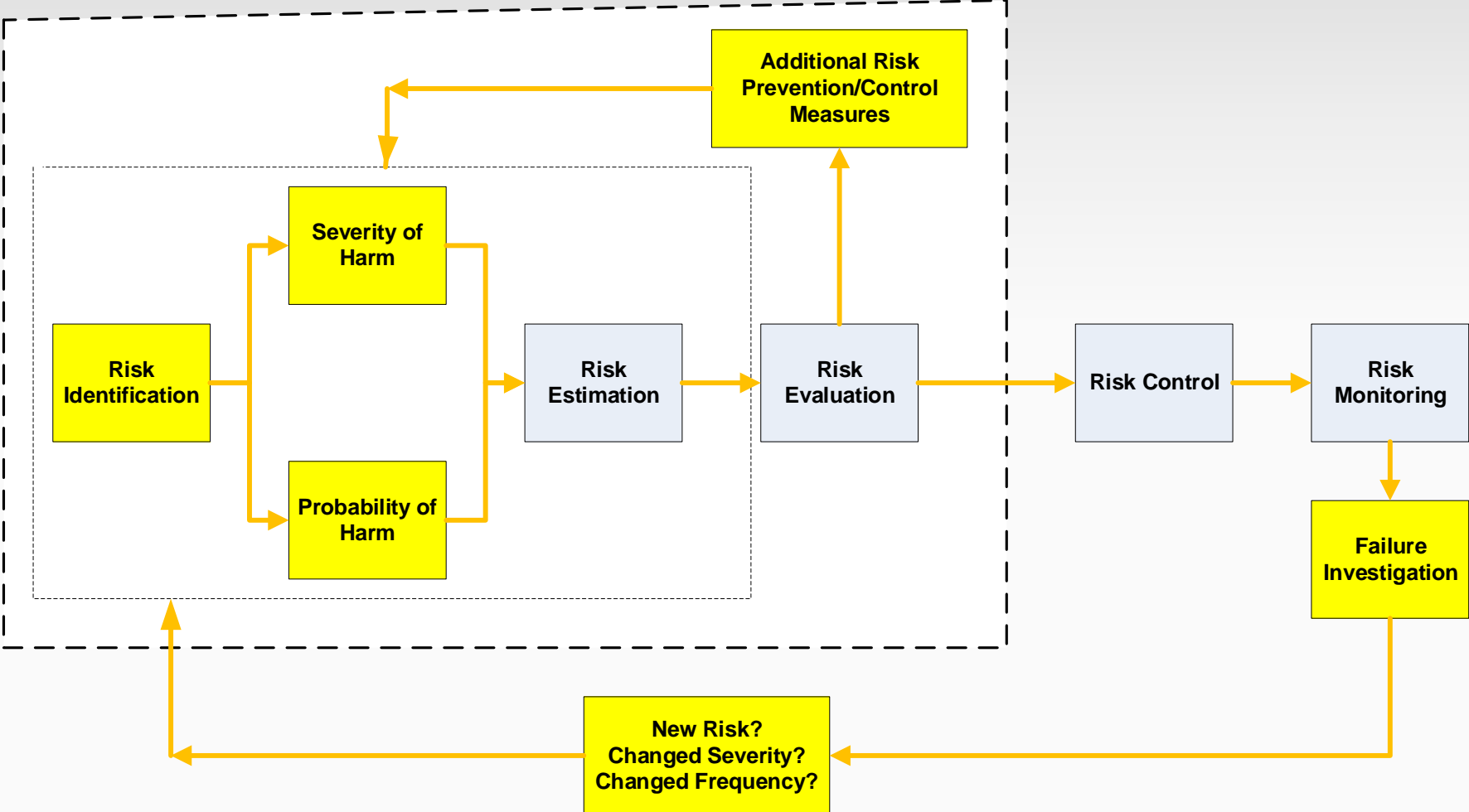
## **Unsatisfactory Outcome :**

When a product that was previously crossmatched incompatible to a patient is crossmatched again to that patient, the system does not display a warning that the product was previously incompatible for the patient. The system preference “Result entry should warn if the product has ever been previously crossmatched to the current patient only if the previous crossmatch result was incompatible?” is set to Yes however this does not always work as intended.

## **Mitigation/Workaround:**

A computer software change is needed to your computer because system cannot perform this functionality in all cases, and a software change is needed. Until changes are made a procedural workaround is put in place, however, as soon as software changes are available from vendor of system, the new version of software should be implemented. Usually this means there will be many changes in the software, all will need to be evaluated for Testing and Validation and this kind of change is usually not within the control of the client and needs help from vendor and takes the most time to implement.

# Risk Management Lifecycle



# Effectiveness

## Post Risk Analysis/CAPA Implementation Review

1. Achieved Desired Outcome?
2. Shift To Acceptable Location On Risk Matrix?
3. Repeat?



## Summary

- Document all decisions for future reference
- Remember that not all risks can be eliminated or mitigated completely
- Some risks just have to either be accepted or realize that the risk is too great to continue