Tony C. Chan
Professor & Director
Risk Management Programs
Center for Applied Health Sciences

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Hong Kong Convention and Exhibition Centre

Total Life Cycle Risk Management
of
Medical Devices

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Center for Applied Health Sciences

- Graduate degree program in Health Product Risk Management through distance learning
- Symposia on Risk Management
- Public Seminars
- Corporate Training Programs
- Corporate Sponsorship Programs
- Accredited Training (CEU's) granted for all controlled training delivered
- Prof. Chan have developed the materials and provide "train the trainer training"

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Faculty for Risk Management

Tony C. Chan, MBA, MSQA, MRS

- Director of Risk Management Program Development and HACCP
- Advisor to the Global Harmonization Task Force, U.S. Co-Chair for the ISO/TC210, JWG1 - Risk Management, advisor to FDA CDRH Medical Device HACCP Program, AHWP
- Founder and trainer of the Orange County Regulatory Affairs' Risk Management Forum
- Trainer on Risk Management to the Association for the Advancement of Medical Instrumentation, Advanced Medical Technology Association, Beijing Hua Guang Certification of Medical Devices Co. Ltd., Hong Kong Productivity Council, Taiwan Industrial Technology Research Institute, Taiwan Parenteral Drug Association, and Enhealth Sdn Bhd., Malaysia.
- Former Quality Development Advisor at Guidant responsible for setting up Quality Risk Management Systems; recognized by US FDA CDRH as industry standard
- 7 Professional Certifications from American Society for Quality (ASQ)

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Presentation Description

- This presentation covers:
  - An overview of ISO 14971:2007 Application of Risk Management to Medical Devices
  - Key Risk Management Terminology
  - Essential Risk Management Concepts
  - Total Life Cycle Risk Management
  - Using medical device codes to close the loop

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Purpose

- This presentation designs to help you to:
  - Understand the fundamental requirements of ISO14971:2007
  - Apply key risk management concepts
  - Use codes to link risk management activities

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Overview of ISO 14971:2007

Scope:

- Applicable to all stages of the product life cycle
- Does not apply to clinical judgment
- Does not specify acceptable risk levels

General Requirements:

- **Top management shall provide evidence of commitment:**
  - Adequate resources
  - Qualified personnel
- **Top management shall:**
  - Establish policy for determining risk acceptability criteria
  - Review the suitability of the risk management process at planned intervals

Risk Mgmt. Process:

- Risk Analysis
- Risk Evaluation
- Risk Control
- Production & Post-Production Information

Qualification of personnel:

- **Knowledge & experience**
  - Medical device & its use
  - Technologies involved or risk management techniques

Documentation:

- Risk Mgmt. Policy
- Risk Mgmt. Plan
- Risk Mgmt. Report
- Risk Mgmt. Review
- Risk Mgmt. File

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Key Terms & Definitions

- **Harm**
  - Physical injury and/or damage to the health of people or damage to property or the environment
- **Hazard**
  - Potential source of harm
- **Hazardous Situation**
  - Circumstances in which people, property or the environment are exposed to a Hazard(s)
- **Severity**
  - Measure of the possible consequences of a Hazard

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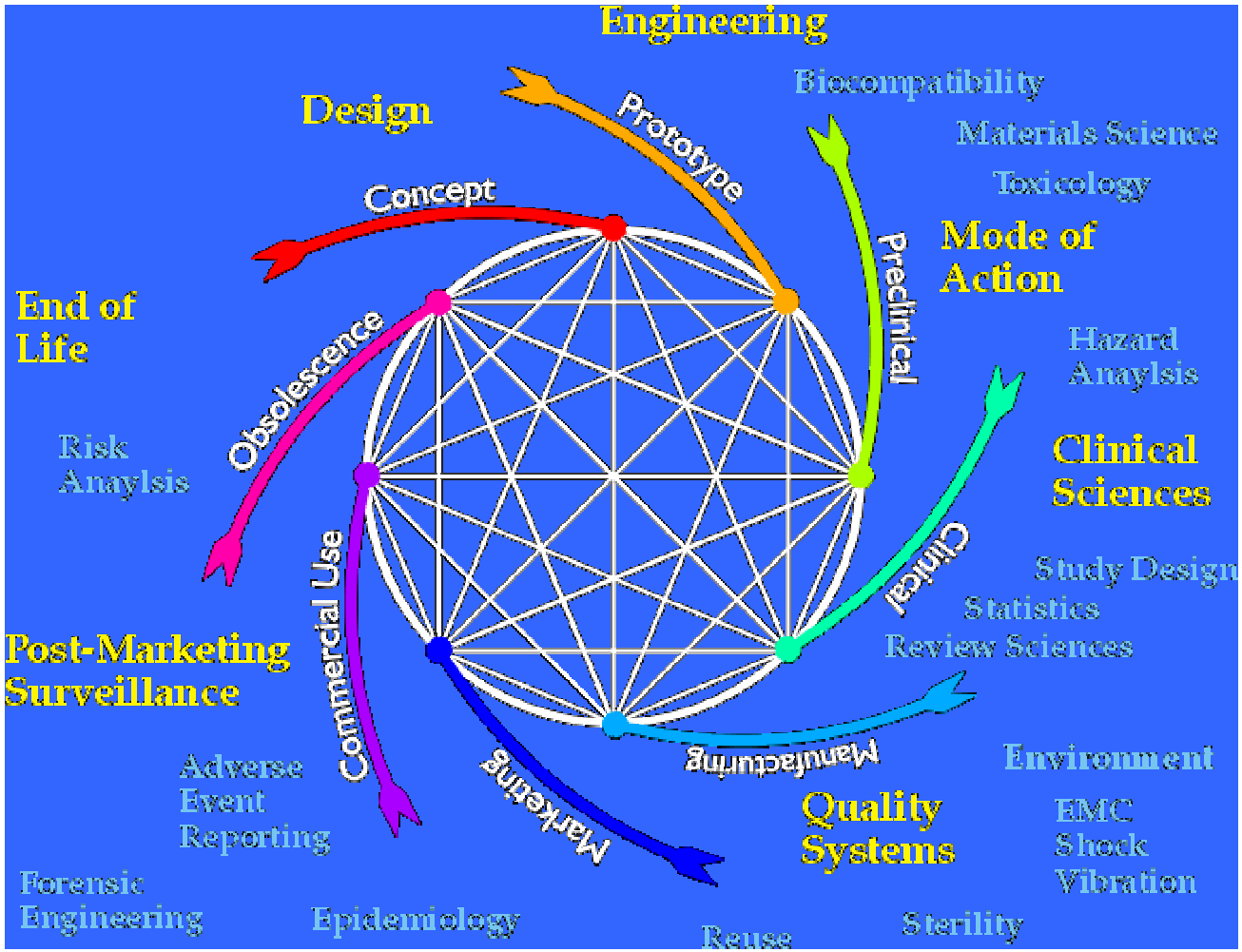
Total Product Life Cycle

(Source: US FDA CDRH 2001)



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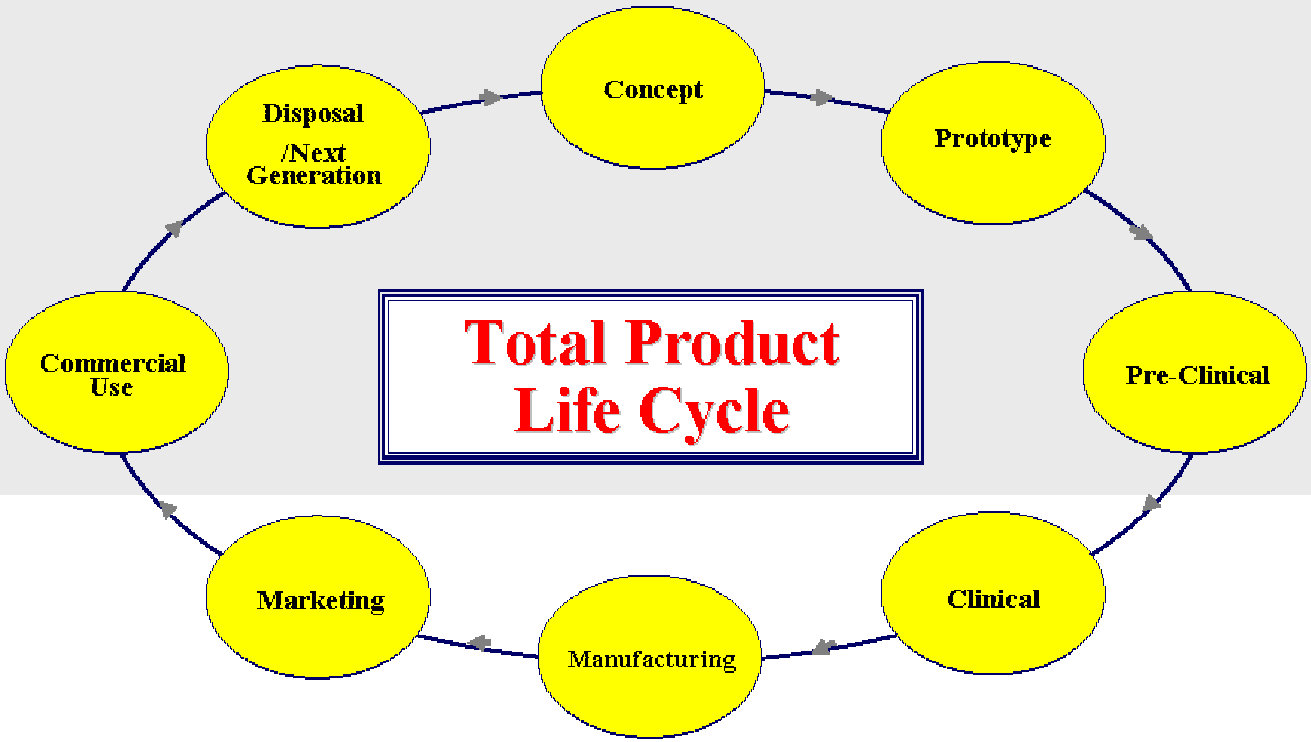
Essential Risk Management Concepts

Life-cycle:

All phases in the life of a medical device, from the initial conception to final decommissioning and disposal.



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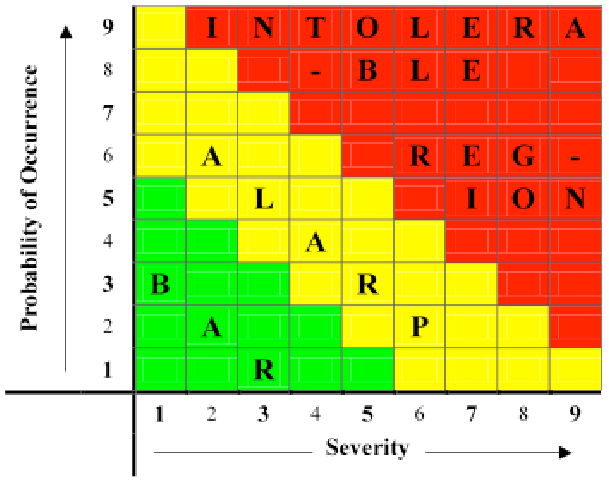
Essential Risk Management Concepts

- **Risk Concept**

  Risk is the combination of two elements:

  - the Probability of the Occurren of harm
  - the Severity of that harm

- **Probability and Severity should be analyzed separately**



- Intolerable Region
- As Low As Reasonably Practicable Region (ALARP, Annex D.8)
- Broadly Acceptable Region (BAR)

As Low As Reasonably Practicable (ALARP)

- **Practicability refers to the ability of a manufacturer to reduce the risk and has two components:**
  - Technical practicability
  - Economic practicability
- **Risk should be reduced even at considerable cost.**
  - Balance between risk and benefit
  - As Low As Reasonably Practicable Region or (ALARP)

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Applications of ISO 14971:2007

Roles & Responsibilities

Technical Staff

1. Risk
2. Assessment
3. Control
4. Effectiveness

Management

1. Review
2. Acceptance
3. Communication
4. Efficiency

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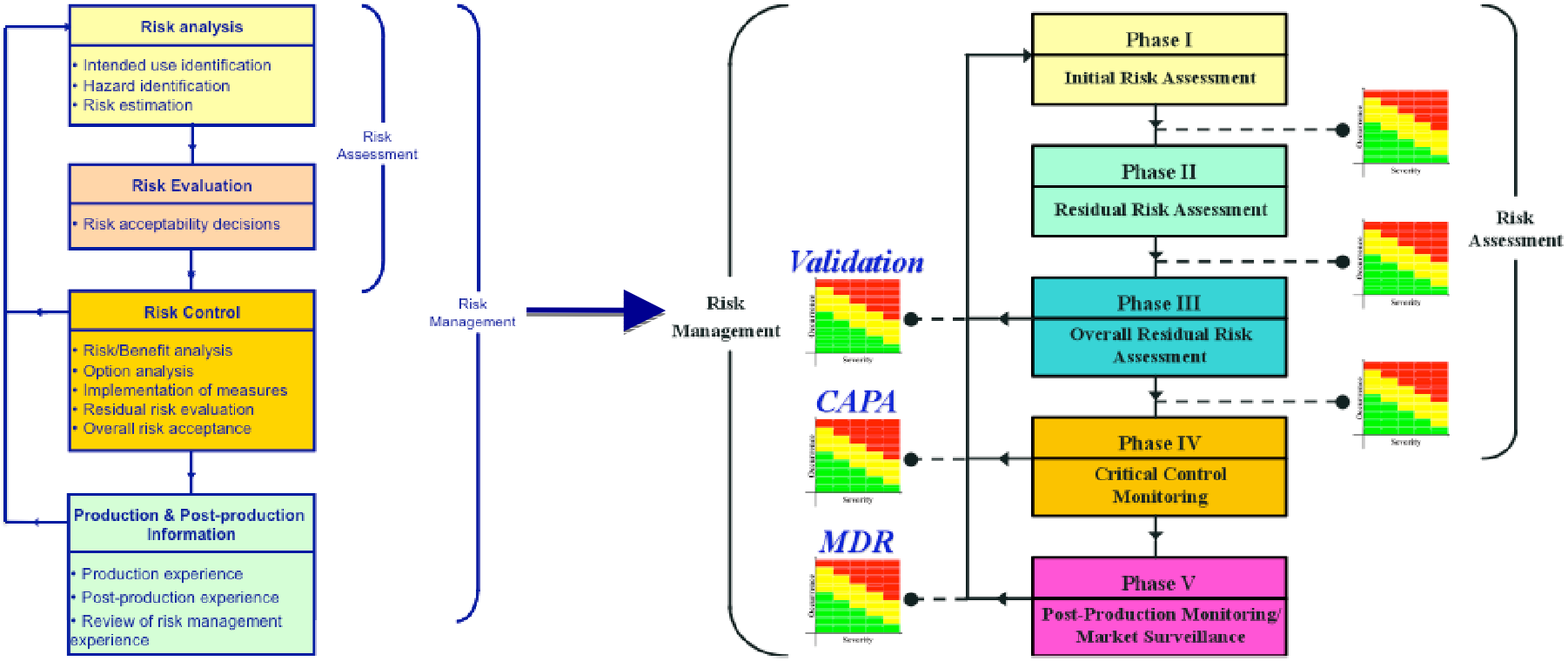
Applications of ISO 14971:2007



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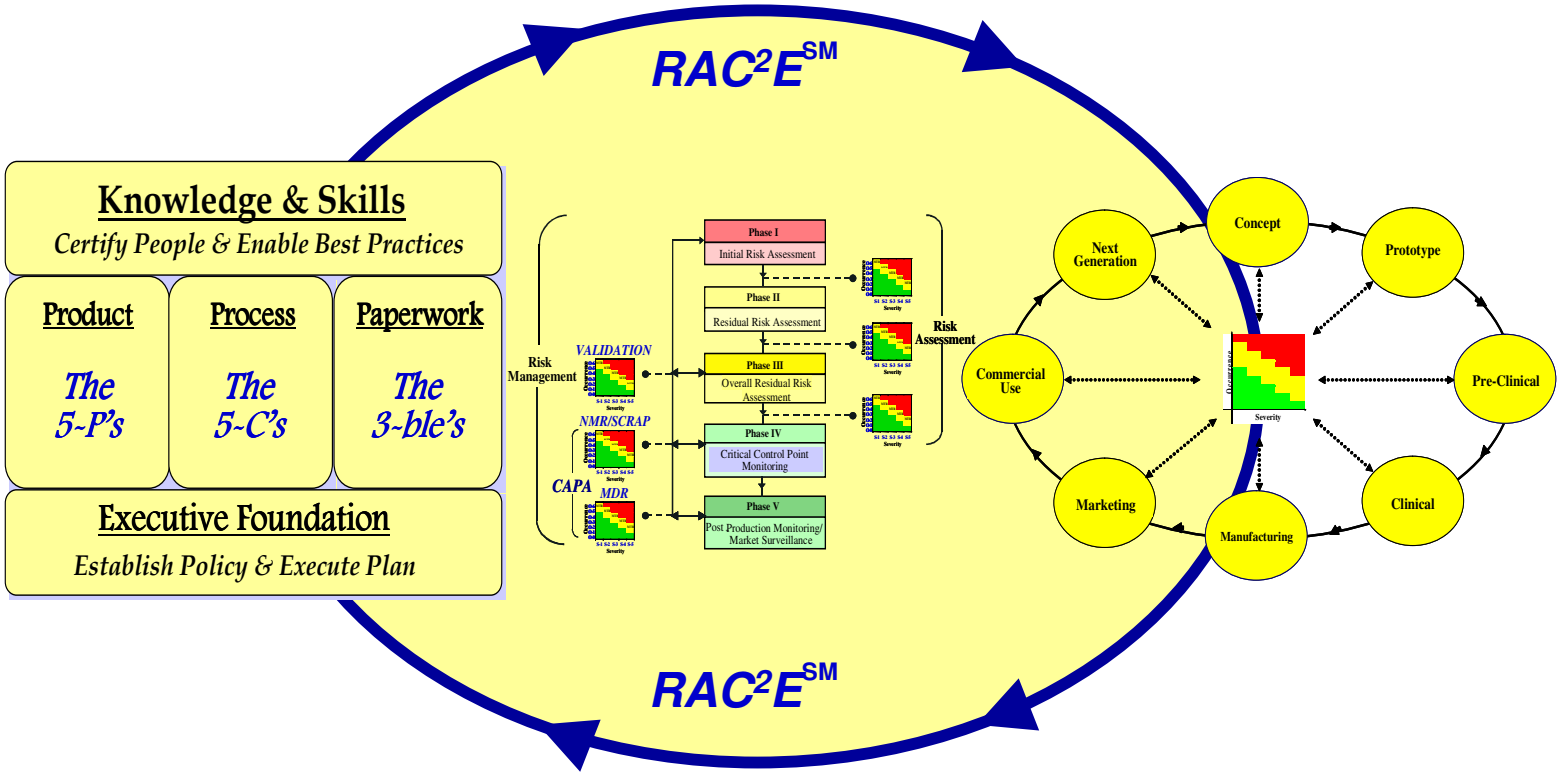
Total Life Cycle Risk Management



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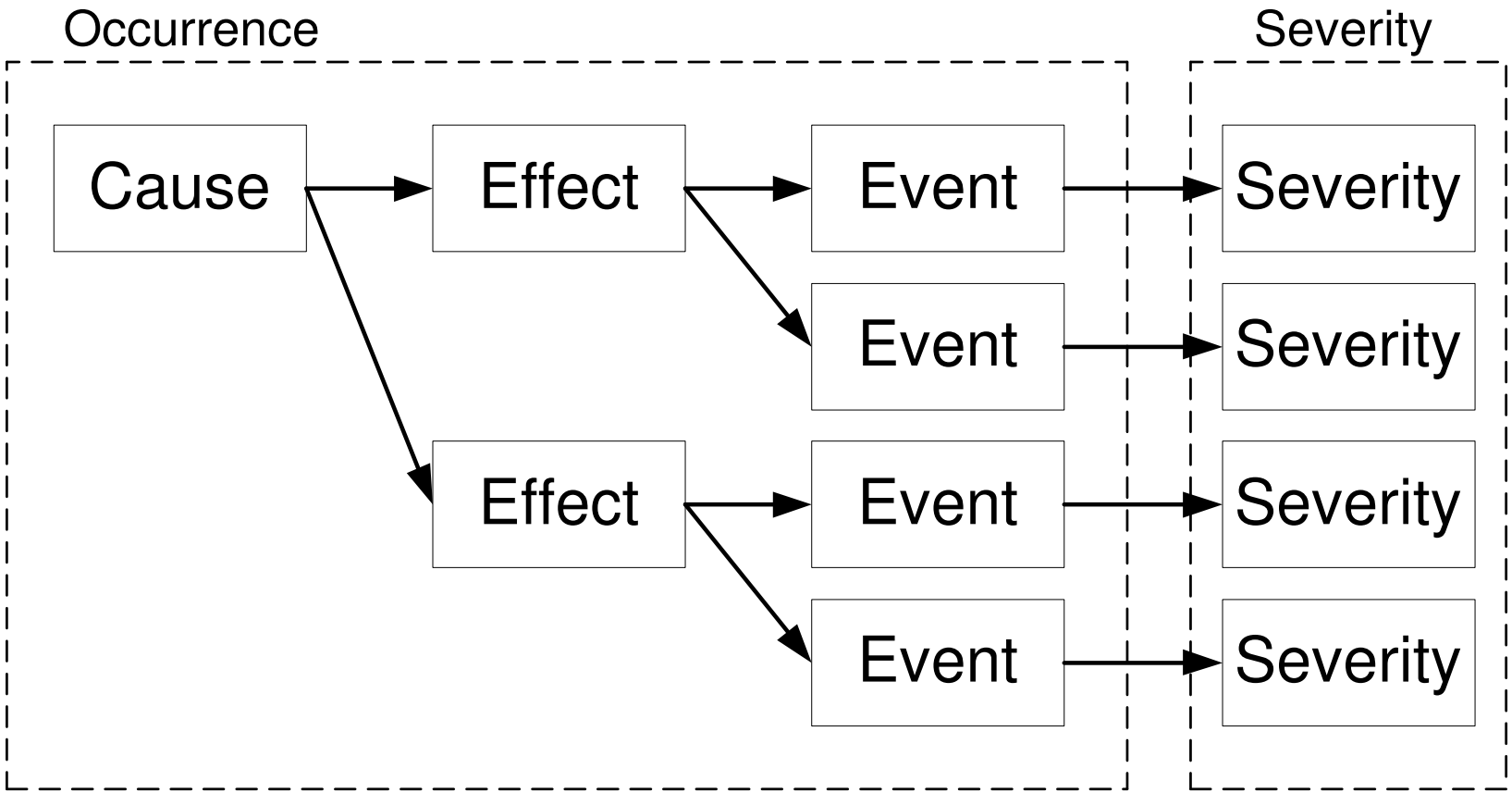
Using Codes to Close the Loop

Occurrence and Severity



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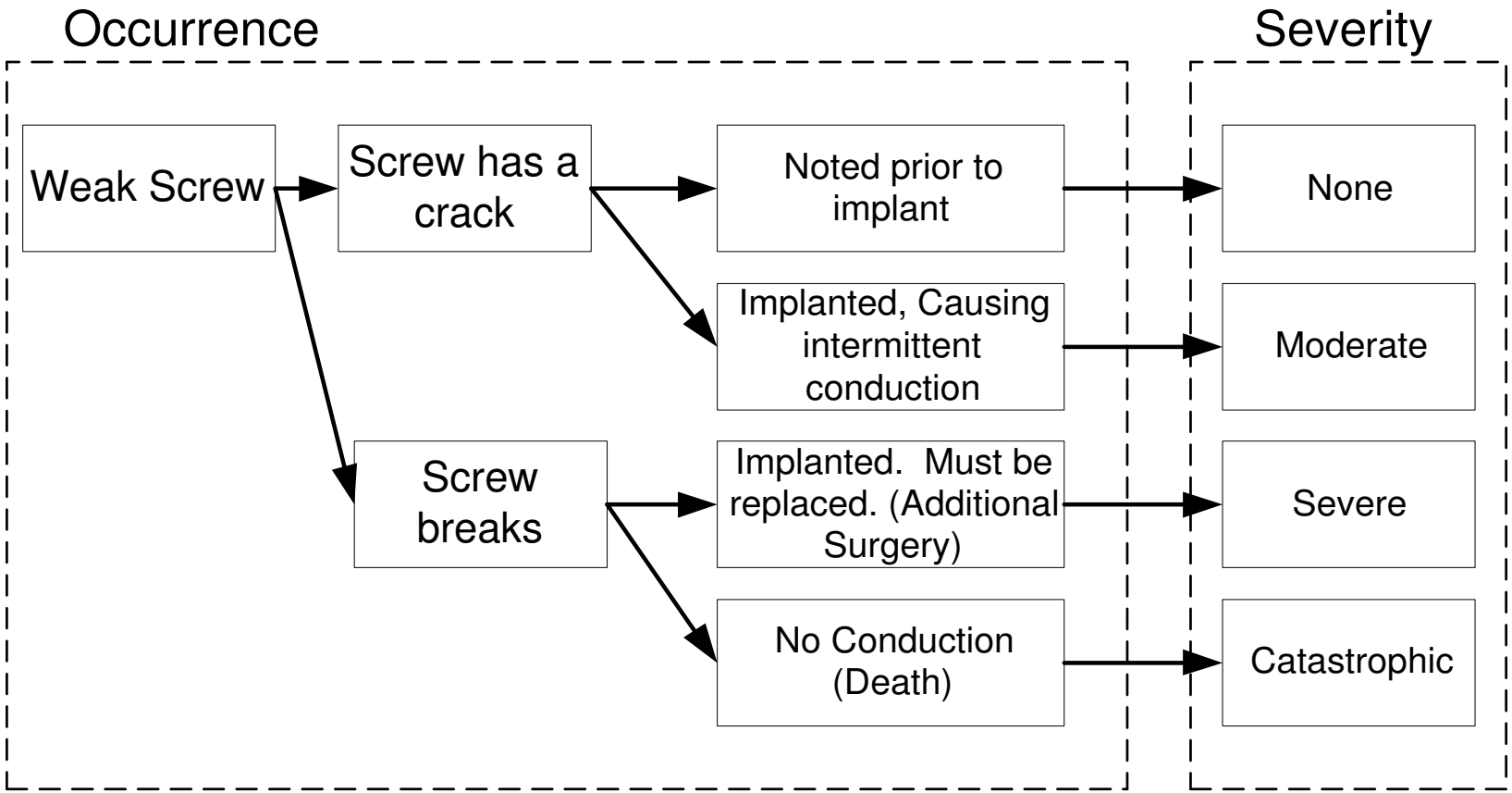
Using Codes to Close the Loop

Identify Sequence of Events



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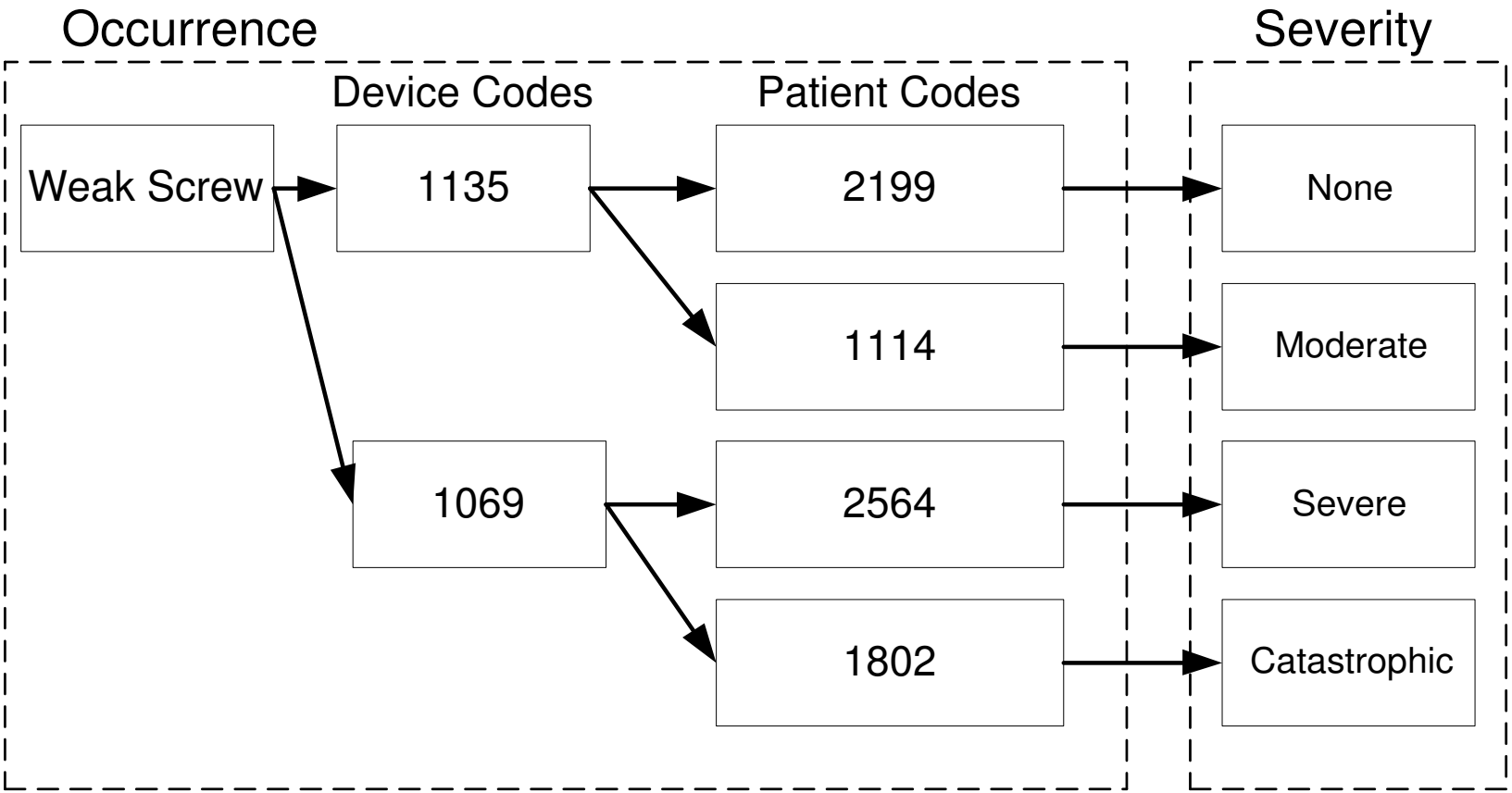
Using Codes to Close the Loop

Substitute Codes



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Occurrence

Occurrence should be translated into a rating to reflect how often this may occur.

O - 1	Event has not been and is not expected to be observed.
O - 2	Event happens at an extremely rare occurrence
O - 3	Event happens at a rare occurrence
O - 4	Event seldom happens
O - 5	Event happens occasionally or more

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Severity

- The severity level is an objective way to look at how much did this event impact the patient
- Severity is determined by asking, if this event occurs, how will it most likely affect the patient.
- Severity is determined by asking how did this event affect the patient.

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Severity

S - 1	(Risk Management) Would most likely result in no patient effect. This event is not expected to cause any effect to patien and/or cause only user dissatisfaction. (Complaints) Had no patient effect. There is nothing in the event that suggests that the patient was effected by the occurrence of the event.
S - 2	(Risk Management) Would most likely result in minimal patient effects. This event is likely to result in a minor injury that resolves without treatment. (Complaints) Had minimal patient effect that resolved without treatment such as transient symptoms.
S - 3	(Risk Management) Would most likely result in moderate patient effects. This may require minor treatment to resolve. N long-term therapy is required. (Complaints) This resulted in a moderate patient effect. The physician or health care worker was able to resolve the situ by applying additional, unexpected treatment in the same setting to resolve the issue.
S - 4	(Risk Management) Would most likely result in serious patient effects. This may require major intervention to resolve. L term follow-up therapy may be required. (Complaints) This resulted in a serious patient effect. The physician or health care worker was not able to resolve the i in the same setting and must perform an additional, unexpected procedure in order to resolve the issue.
S - 5	(Risk Management) Would most likely result in serious, permanent impairment or death. (Complaints) This resulted in permanent impairment such as loss to a body function or structure. The physician or heal care worker was unable to avoid such permanent impairment.

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Using Codes to Close the Loop

Risk Chart

O-5	2199				
O-4			1114		
O-3					
O-2				2564	1802
O-1					
	S-1	S-2	S-3	S-4	S-5

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Using Codes to Close the Loop

Initial Risk Assessment

Number	Cause	Effect	Event	Severity	Occur	Risk	Risk Mitigation Activity	Severity	Occur	Risk
1.1	Weak Screw	1135	2199	S1	O4	Med				
1.2			1114	S3	O5	High				
1.3		1069	2564	S4	O2	Med				
1.4			1802	S5	O2	High				

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Using Codes to Close the Loop

Risk Control Activities

Number	Cause	Effect	Event	Severity	Occur	Risk	Risk Mitigation Activity	Severity	Occur	Risk
1.1	Weak Screw	1135	2199	S1	O4	Med	Supplier Development, Microscopic examination of screw upon receipt prior to acceptance			
1.2			1114	S3	O5	High				
1.3		1069	2564	S4	O2	Med				
1.4			1802	S5	O2	High				

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Using Codes to Close the Loop

Risk Chart

O-5					
O-4					
O-3					
O-2	2199		1114		
O-1				2564	1802
	S-1	S-2	S-3	S-4	S-5

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Using Codes to Close the Loop

Residual Risk Assessment

Number	Cause	Effect	Event	Severity	Occur	Risk	Risk Mitigation Activity	Severity	Occur	Risk
1.1	Weak Screw	1135	2199	S1	O4	Med	Supplier Development, Microscopic examination of screw upon receipt prior to acceptance	S1	02	Low
1.2			1114	S3	O5	High		S3	02	Med
1.3		1069	2564	S4	O2	Med		S4	01	Low
1.4			1802	S5	O2	High		S5	01	Low

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Customer Complaints

- Now apply the risk chart to the customer complaint system.
  - Assign a Cause, a Device Code, a Patient Code to every complaint.
  - Determine the occurrence and assign an “O” level.
  - Determine the severity and assign an “S” level.
  - Plot the “O” and “S” on the Risk Chart.

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Complaint Example

Item #	Cause	Effect	Event	Severity	Occurrence	Risk level	Risk Mtigation Activity	Severity	Occurrence	Residual Risk
1.1	Bad motivator	6339	9236	S-4	O-3	High				
1.2		6588	2548	S-1	O-3	Low				
2.1	Packing error	7316	6528	S-1	O-2	Low				
2.2		7583	9635	S-3	O-2	Med				
2.3		7703	8882	S-3	O-2	Med				
2.4		8803	6558	S-1	O-2	Low				
3.1	Reading incorrect	6058	1754	S-1	O-2	Low				
4.1	That incorrect	7354	7888	S-2	O-3	Med				
4.2		7467	8854	S-3	O-2	Med				
4.3		7798	9569	S-4	O-2	Med				
4.4		8385	7541	S-2	O-2	Low				

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Risk Chart with Complaints

O-5					
O-4					
O-3	1.2, 2.1	4.1		1.1	
O-2	2.1, 2.4, 3.1	4.4	2.2, 2.3, 4.2	4.3	
O-1					
	S-1	S-2	S-3	S-4	S-5

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Conclusions

- Every complaint has a Cause, Effect and Event associated with it.
- Complaints could be coded to close the loop between the initial risk assessment and field events.
- There are other stages in the product life cycle to be coded, such as CAPA etc.
- These codes may link with UDI for other purposes.

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Questions??

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Professor & Director
Risk Management Programs
Center for Applied Health Sciences

Follow-Through

Contact Information:

- E-Mails: ChanT@VT.edu or TChan@AGSM-Inc.com
- Phones: (Asia) +852-819-77-318
(USA) +1-714-779-8298