# Wrangling the HUMAN element of interoperability

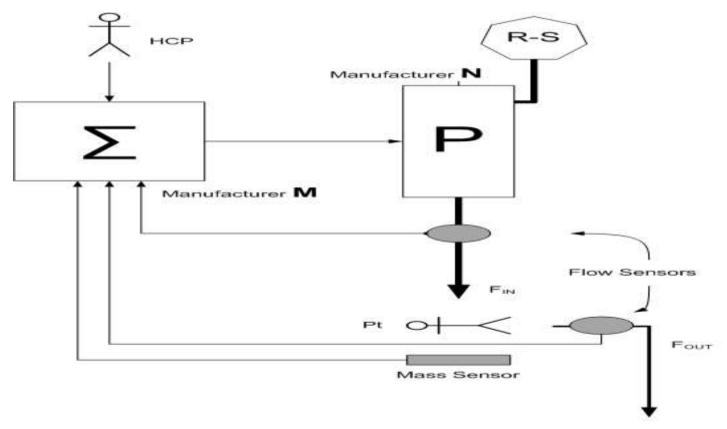
Defending against

Reason's latent flaws & Dekker's drift

## Burn Pt Fluid Vol. Mgmt.

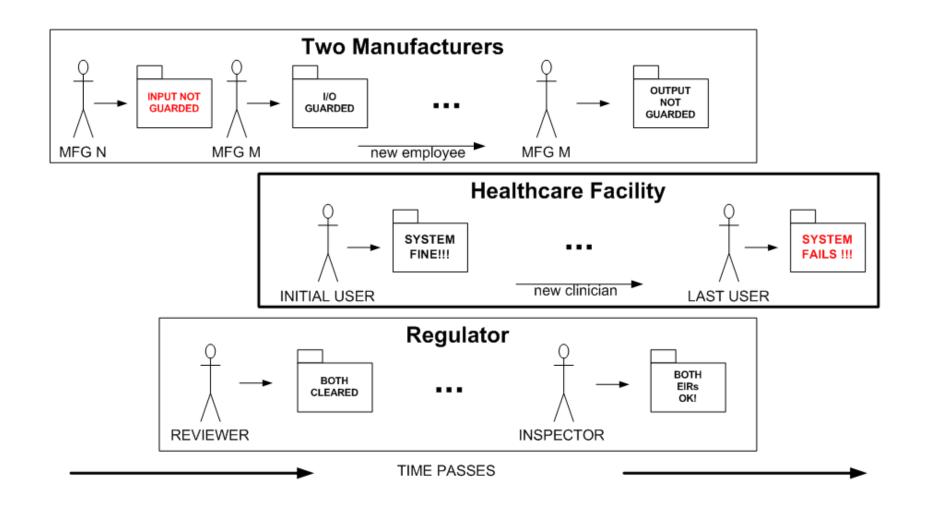
- Scenario is fictitious
  - But NOT a fiction!!
- Cascade of events actually occurred
  - This is illustrative of problem

## Clinical Use Scenario



Worked fine, then didn't!!!

# What Happened?



## Whom do we blame?

REVIEWER?	Watch administrative clearances grind to a halt
INSPECTOR?	NOT trained or resourced to detect this!
INITIAL USER?	It worked just fine!
LAST USER?	Used per manufacturers' instructions
Manufacturer N?	Maybe, maybe not – Tell that to the plaintiff's bar
Manufacturer M?	Eng #1: Absolutely NOT! Eng #2: What's the benefit??
Management?	Always! (manufacturers, facility, regulators, HCPs)  Always remember to sue everyone ©

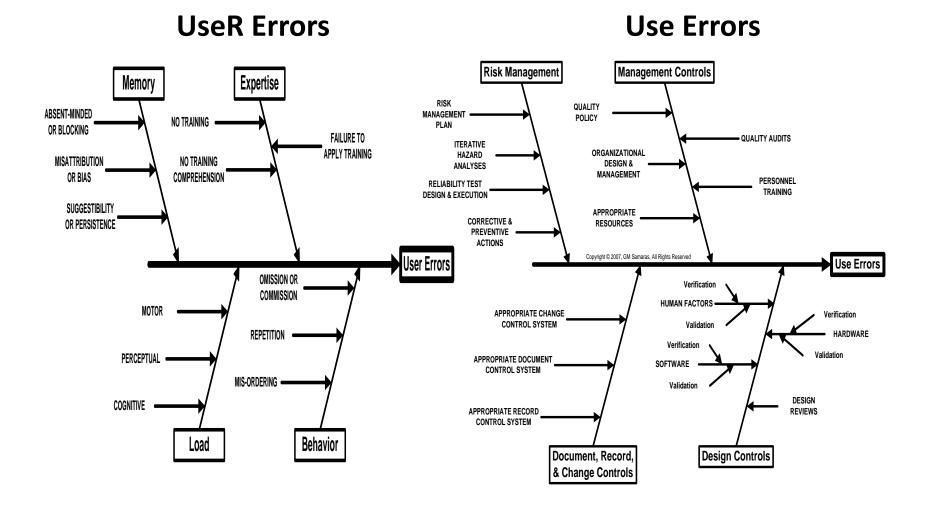
This was, <u>and will continue to be</u>, a **SYSTEMIC** failure
The **COMPONENT** failures are merely **SYMPTOMS**It **WILL** get worse with increasing system **COMPLEXITY**...

# Why did it happen?

#### **SOME KEY ELEMENTS**

- UseR vs. Use Errors
- Propagated vs. Compounded Errors
  - Disjoint Lifecycles
  - When Design Controls Won't

## UseR vs. Use Errors

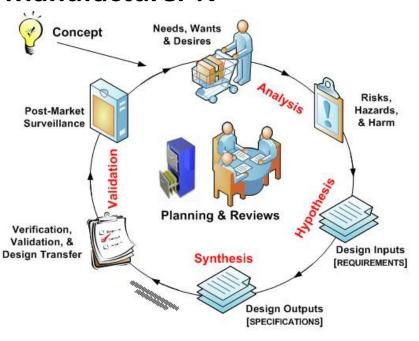


# Propagated vs. Compounded Errors

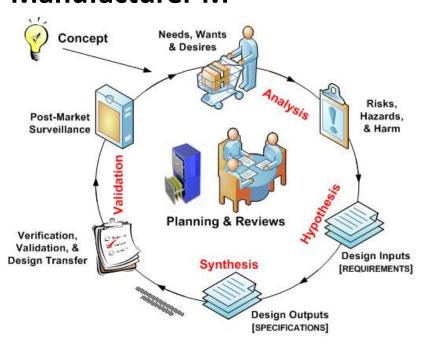
#### **Compounded Errors Propagated Errors** All hazards accessible by validation Hazards #1 & #3 NOT accessible by testing implementation!! testing implementation Hazard #3 appears only after variations in manufacturing, maintenance, etc. Needs Needs (after Dekker, 2005) Design Design Inputs Inputs LATENT FAILURES Design Design (after Reason, 1990) Outputs Outputs 0 after Reason, 1990 Hazard #1 Version Hazard #1 appears only after Version a change in the specifications Realization Realization Hazard #3

# Disjoint Lifecycles

#### Manufacturer N

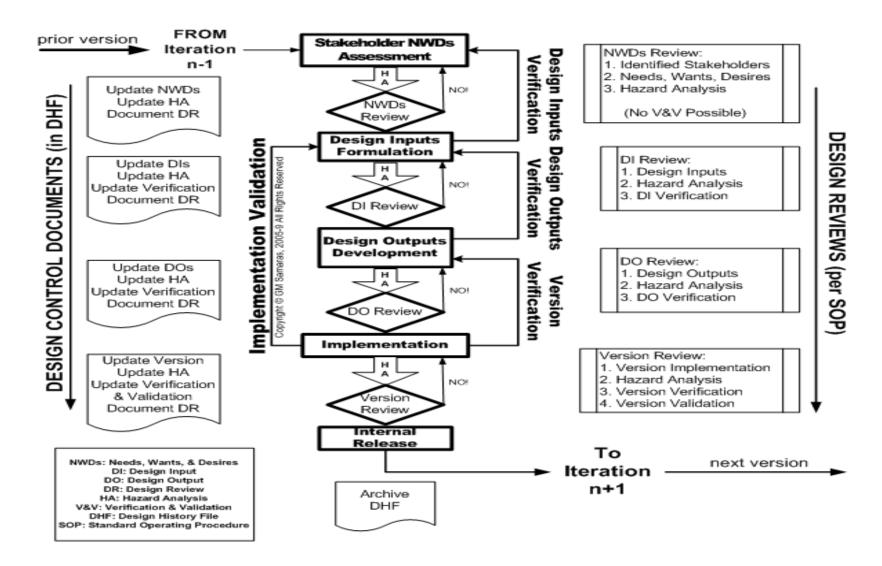


#### Manufacturer M



Guess what would happen if **your suppliers** could make changes without full coordination

# When Design Controls Won't



# Regulatory Challenge

- Failure Loci: humans doing their jobs
- **Failure cause**: defective design inputs resulting in *latent failures* and *specification drift* 
  - Root causes:
  - Lifecycle management inadequate
  - Regulatory emphasis on marketing & manufacturing
- **CONDUNDRUM**: Everybody did their individual job as they understood it!!!
  - RA/RM plus V&V not up to the job!

**CHALLENGE:** Increasing system <u>complexity</u>, resulting from interoperability, means increasing number of catastrophic failures & <u>horrible</u> PR ... on your watch

## **Possible Solutions**

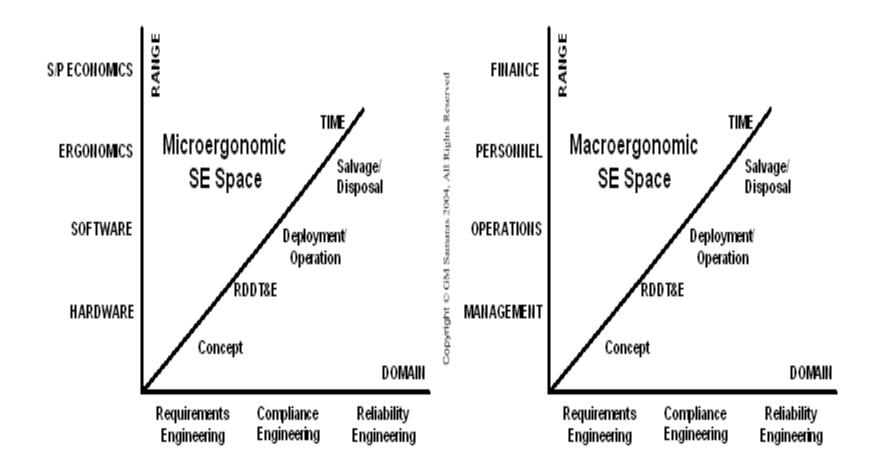
- Shift regulatory emphasis from Mkt & Mfg to lifecycle management
  - Industry mature, only outliers (& newbies) need M&M
  - For regulators, M&M easy, but LM will be difficult
- Greater vigilance by MD manufacturers building "interoperable" devices for:
  - Latent flaws & Drift over full lifecycle "from lust to dust"
- Improved <u>understanding</u> by physicians, managers, engineers, and regulators of:
  - complex system failures and
  - HFE component of ALL stakeholders

## Some Recommended Reading

- Reason J. Human Error. Cambridge University Press. 1990. ISBN 0-521-31419-4
- Dekker SWA. Ten Questions About Human Error: A New View of Human Factors and System Safety. Lawrence Erlbaum Assoc., Inc. 2005. ISBN 0-8058-4745-6
- Dismukes RK, Berman BA, & Loukopoulos LD. The Limits of Expertise: Rethinking Pilot Error and the Causes of Airline Accidents. Ashgate Press. **2007. ISBN 978-0-7546-4965-6**

# Backup Slides

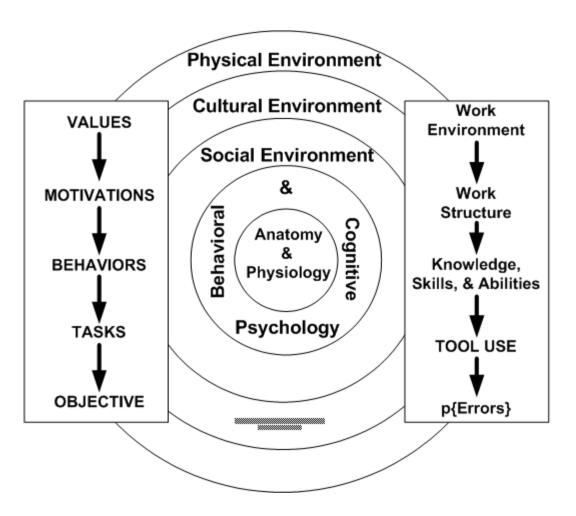
# Micro/Macro-Ergonomic Lifecycles



## **HCSE Common Domains**

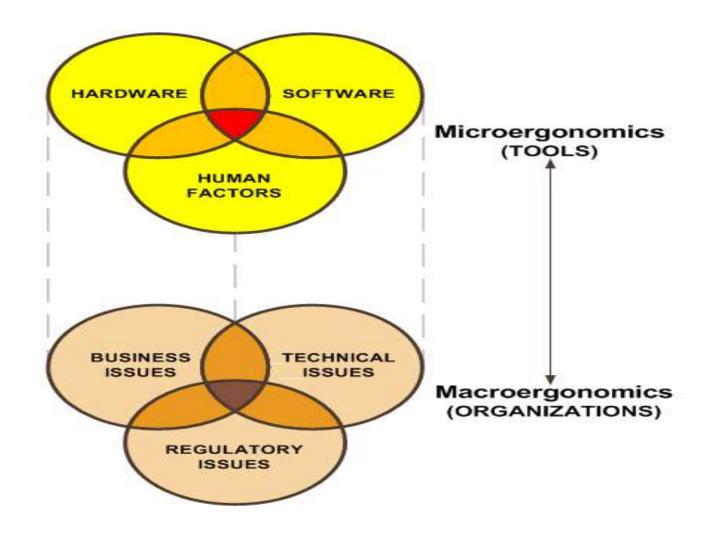
Requirements	Compliance	Reliability
Engineering	Engineering	Engineering
Stakeholder Identification,	Identification of Laws,	Defining Minimum Necessary Reliability
NWD Assessment &	Regulations, &	
Reconciliation	Standards	
Hazard Analyses (Risk	Applicability	Fault Prevention
Mgmt)	Assessment	
Design Input Formulation	Design Impact	Fault Removal
& <b>5</b> Verifications	Assessment	
Version Validation	Test Design	Fault Tolerance
Version Post-Market	Operational	Fault/Failure
Surveillance	Considerations	Forecasting
CAPA-driven Design Input	Salvage and/or Disposal	Test Design
Changes	Considerations	1636 2631811

## Factors for Actors



Operate in complex environment - influences achievements and errors

### **Error Sources & Interactions**



## **Human-Centered System Complexity**

Human(s) OPERATING with Tool(s)

Anthropomorphometry
Biomechanics & Sensory Perception

Human(s) OPERATING with Tool(s) with Automation

Verbal/Non-verbal Behaviors Affective, Cognitive,& Physiological

Human(s) OPERATING within Organization(s)

Communication & Coordination Conventions & Expectations

Human(s) OPERATING within Culture(s)

Language & Artifacts<sup>1</sup>
Beliefs, Customs, Ethics, Morals

<sup>1</sup> Boulding, KE. Ecodynamics. Sage, 1978, p221.

Micro-Ergonomics (Physical Ergonomics)

Overt & Covert Physical Factors

Meso-Ergonomics<sup>2</sup> (Information Ergonomics)

Overt & Covert Behavioral Factors

<sup>2</sup> Shipley,P., Ergon. 41(1) 1998, pg. 7

Macro-Ergonomics (Social Ergonomics)

Overt & Covert Social Factors

Mega-Ergonomics (Cultural Ergonomics)

Overt & Covert Cultural Factors

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System Complexity from Human Factors Perspective