Wrangling the HUMAN element of interoperability

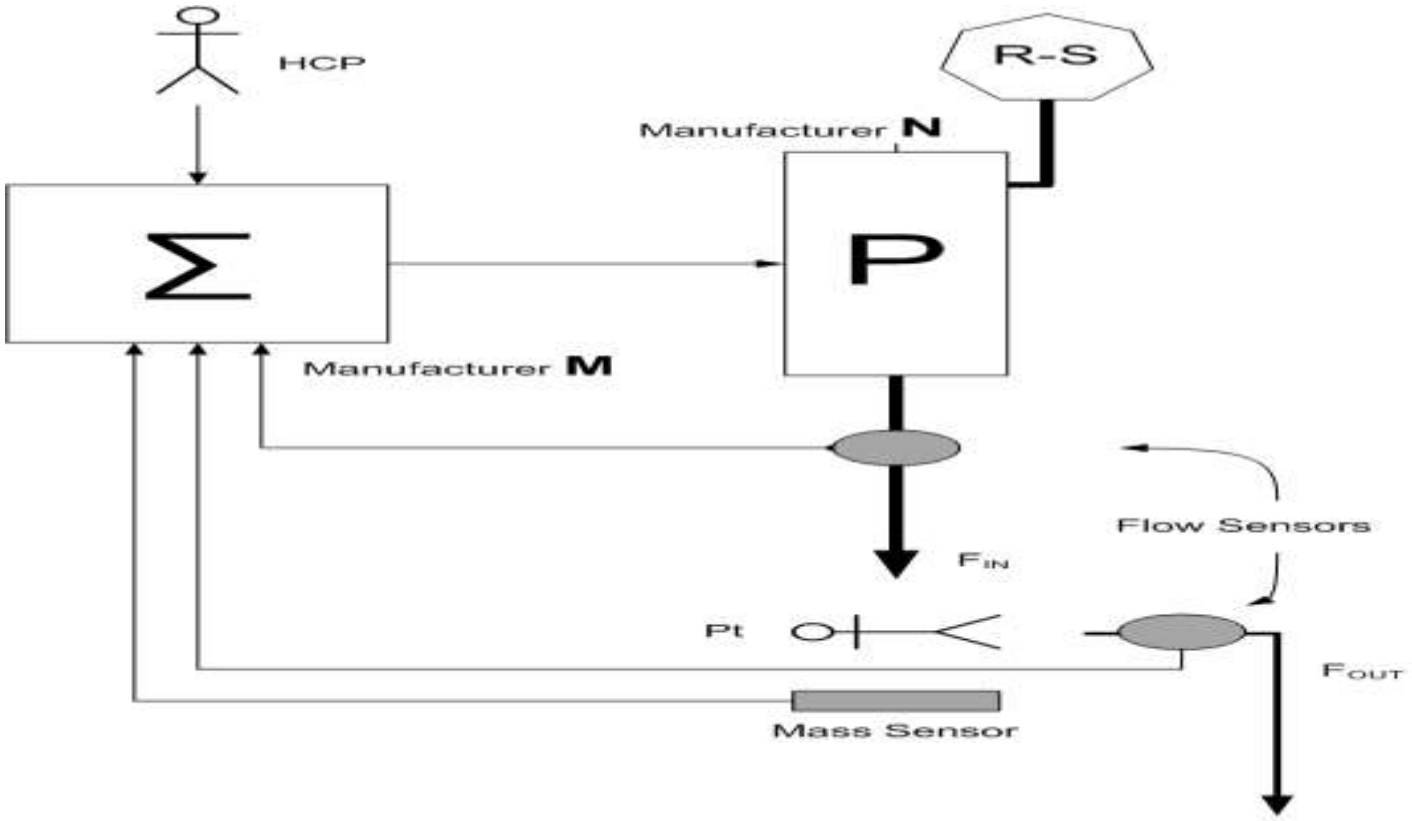
Defending against

Reason's *latent flaws* & Dekker's *drift*

Burn Pt Fluid Vol. Mgmt.

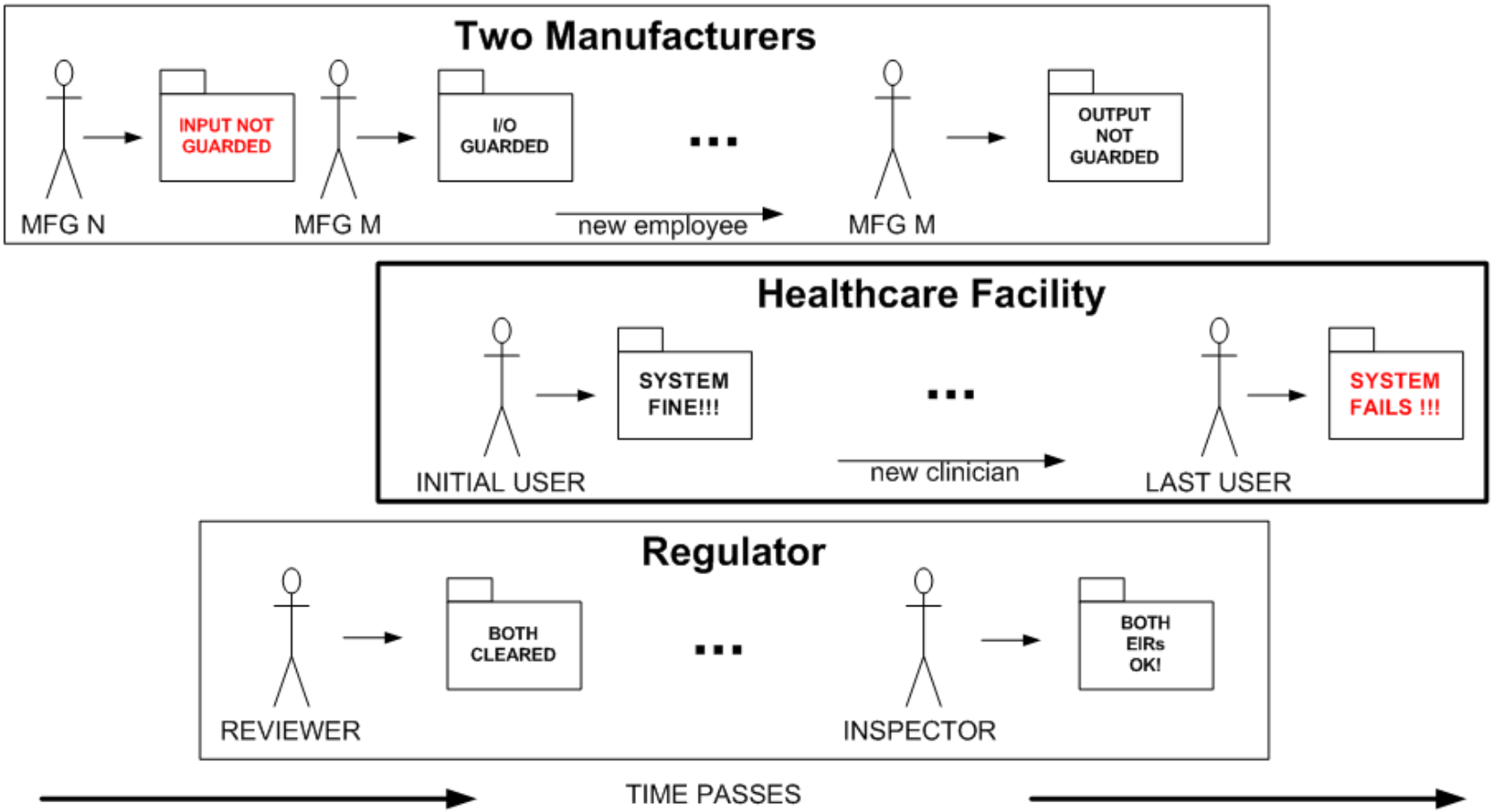
- Scenario is fictitious
  - But NOT a fiction!!
- Cascade of events actually occurred
  - This is illustrative of problem

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* ☺

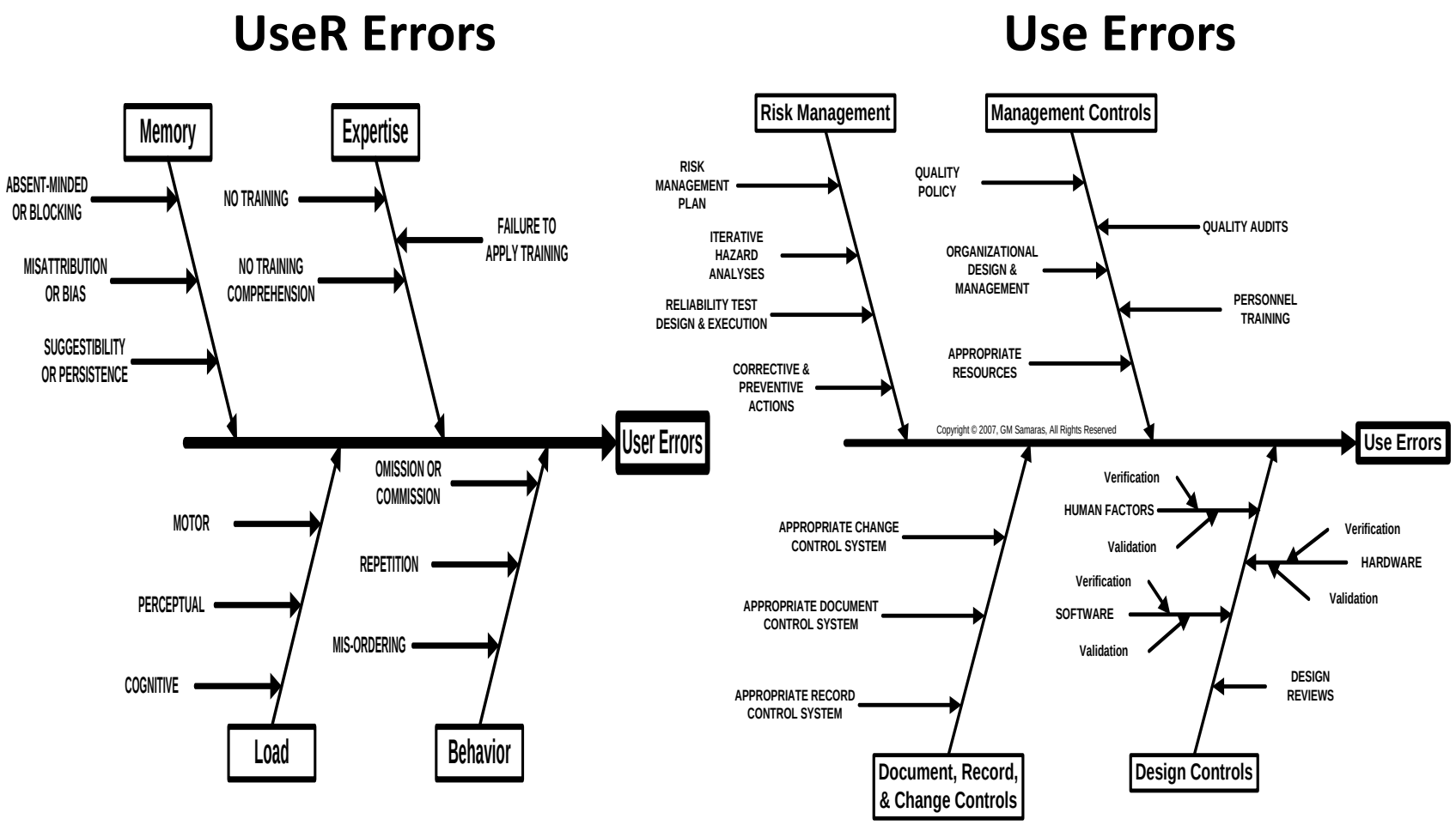
This was, *and will continue to be*, a **SYSTEMIC** failure
The **COMPONENT** failures are merely **SYMPTOMS**
It **WILL** get worse with increasing system **COMPLEXITY**…

Why did it happen?

SOME KEY ELEMENTS

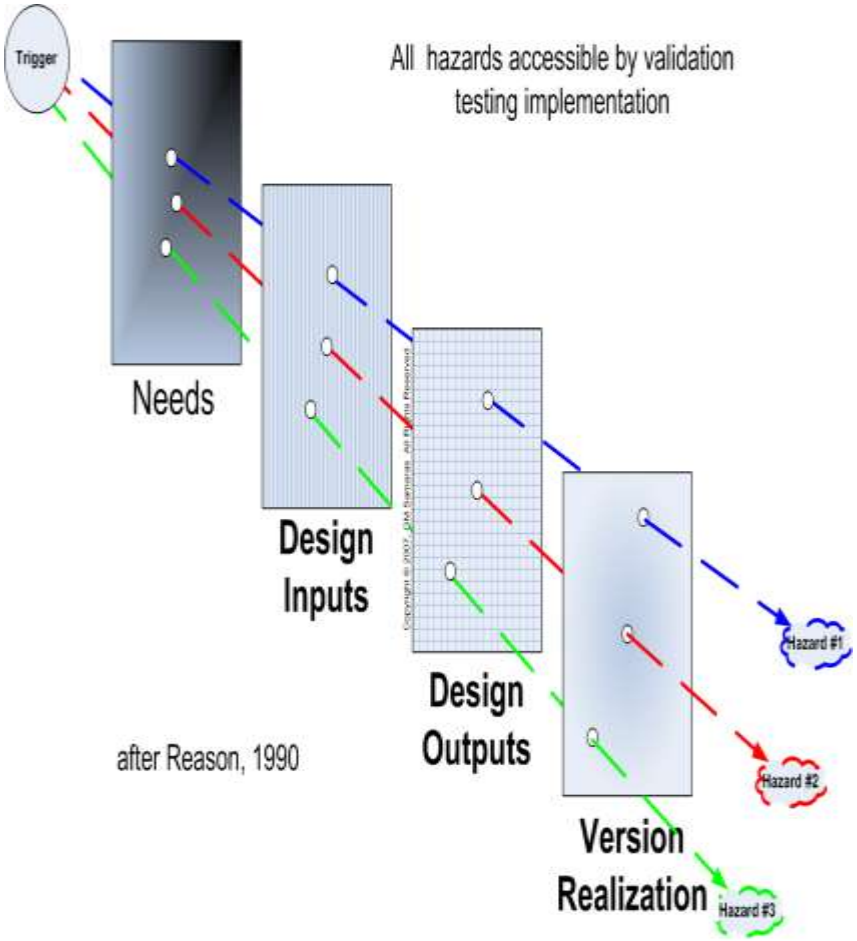
- UseR vs. Use Errors
- Propagated vs. Compounded Errors
- Disjoint Lifecycles
- When Design Controls Won't

UseR vs. Use Errors

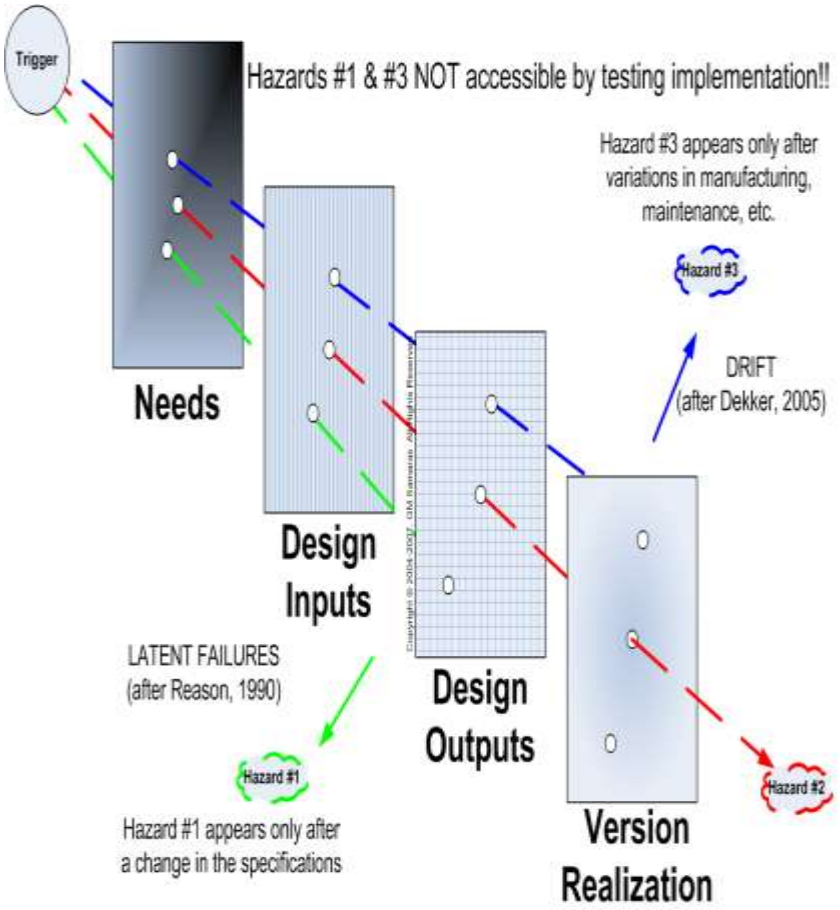


Propagated vs. Compounded Errors

Propagated Errors

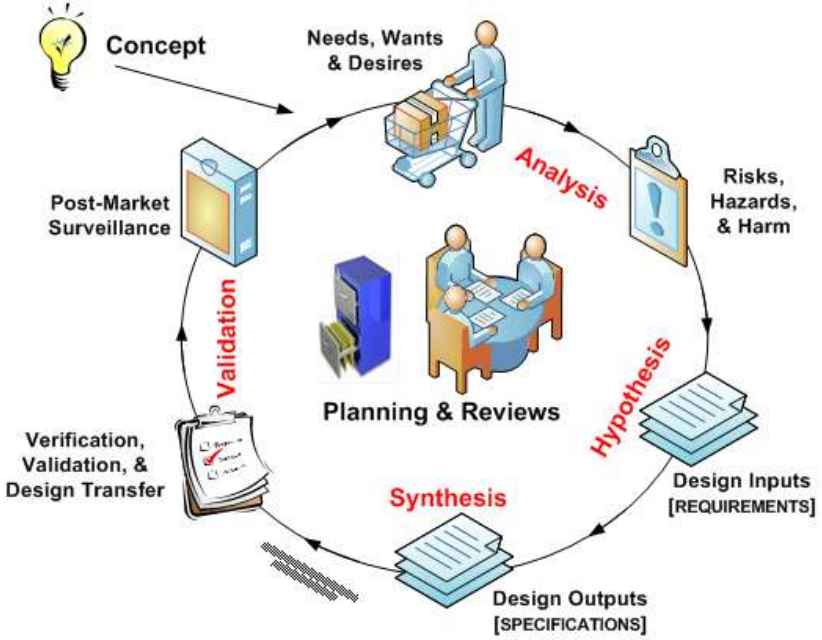


Compounded Errors

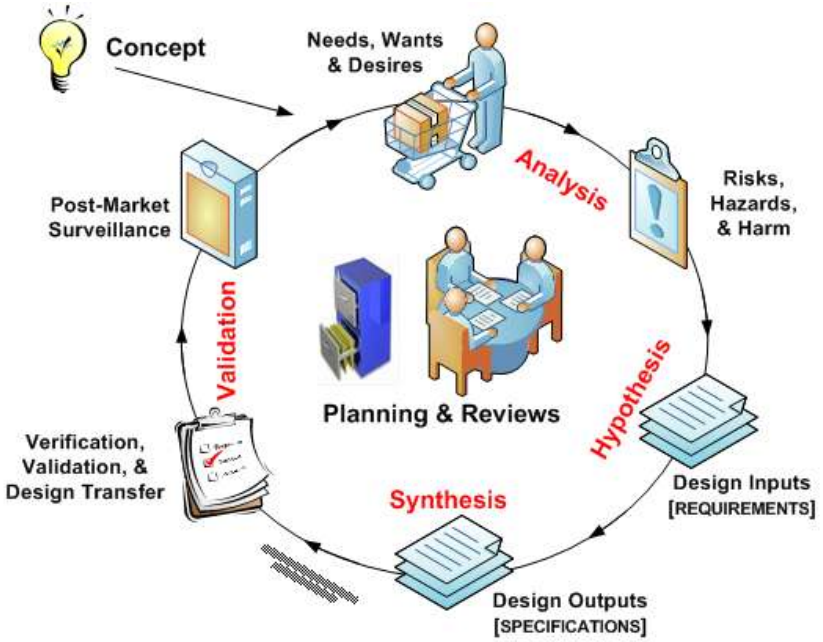


Disjoint Lifecycles

Manufacturer N

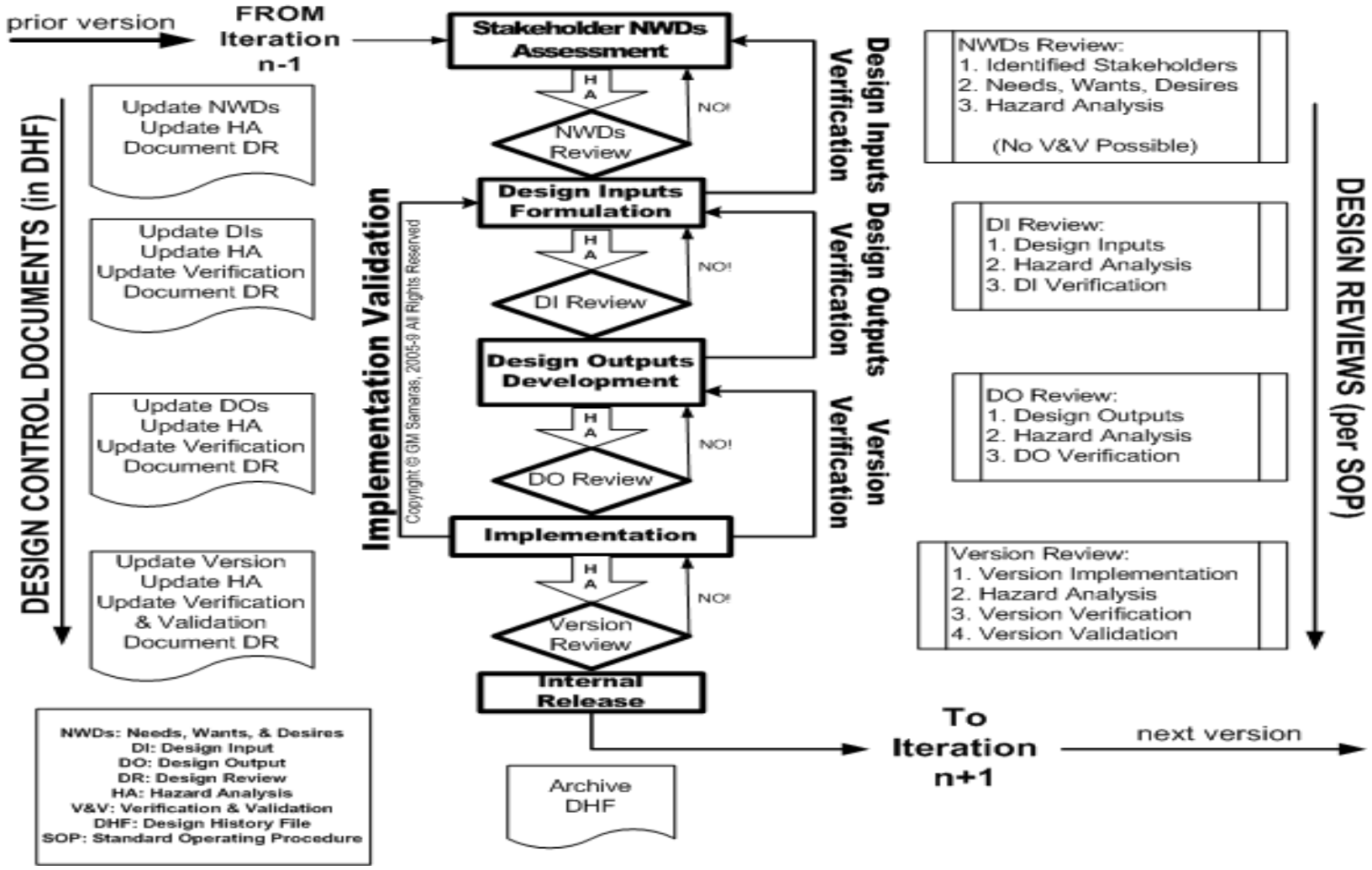


Manufacturer M



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 complexity, resulting from interoperability, means increasing number of catastrophic failures & horrible 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 **understanding** by physicians, managers, engineers, and regulators of:
  - complex system failures and
  - HFE component of ALL stakeholders

Some Recommended Reading

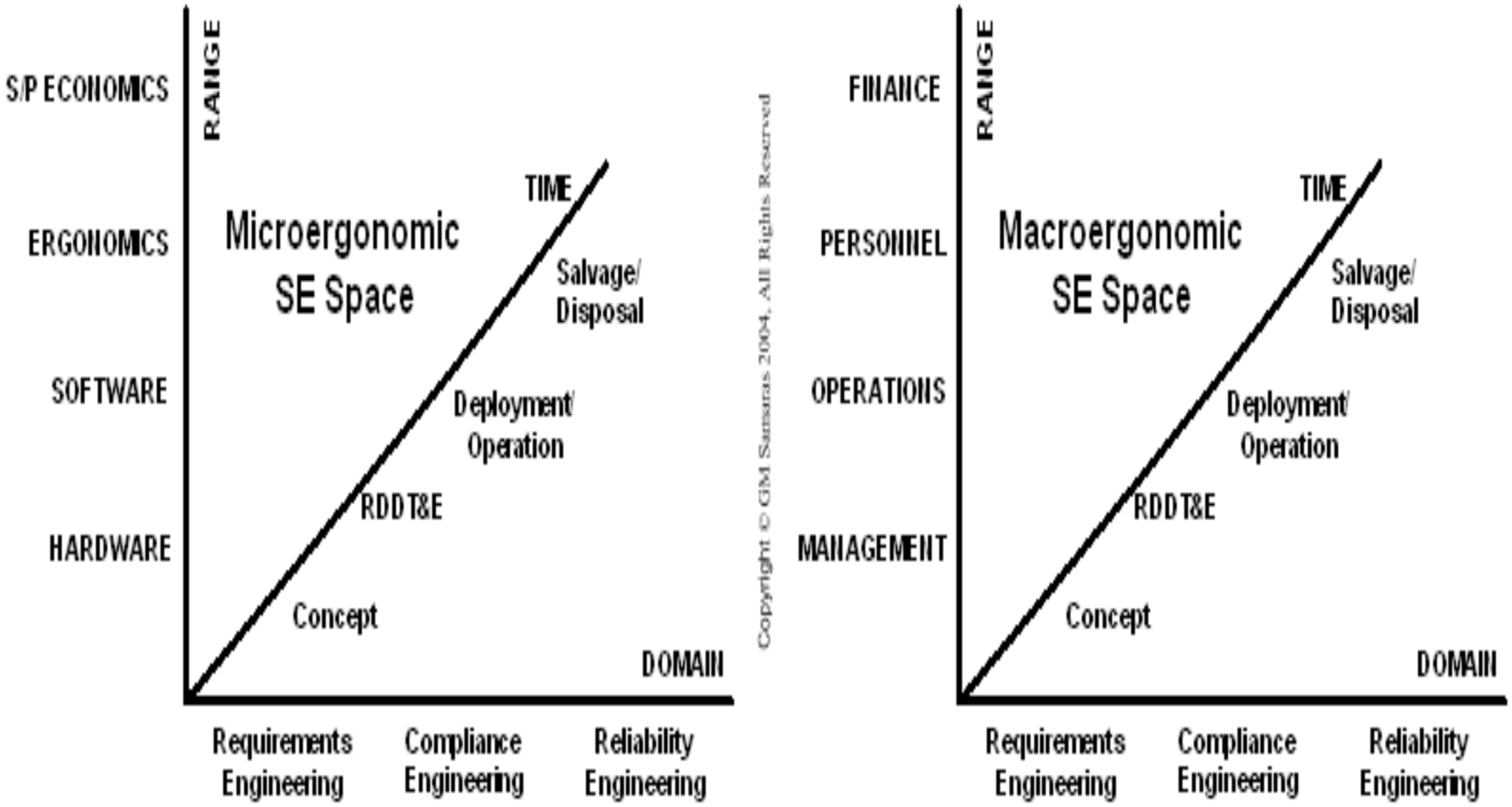
- Reason J. Human Error. Cambridge University Press. **1990. ISBN 0-521-31419-4**

- 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

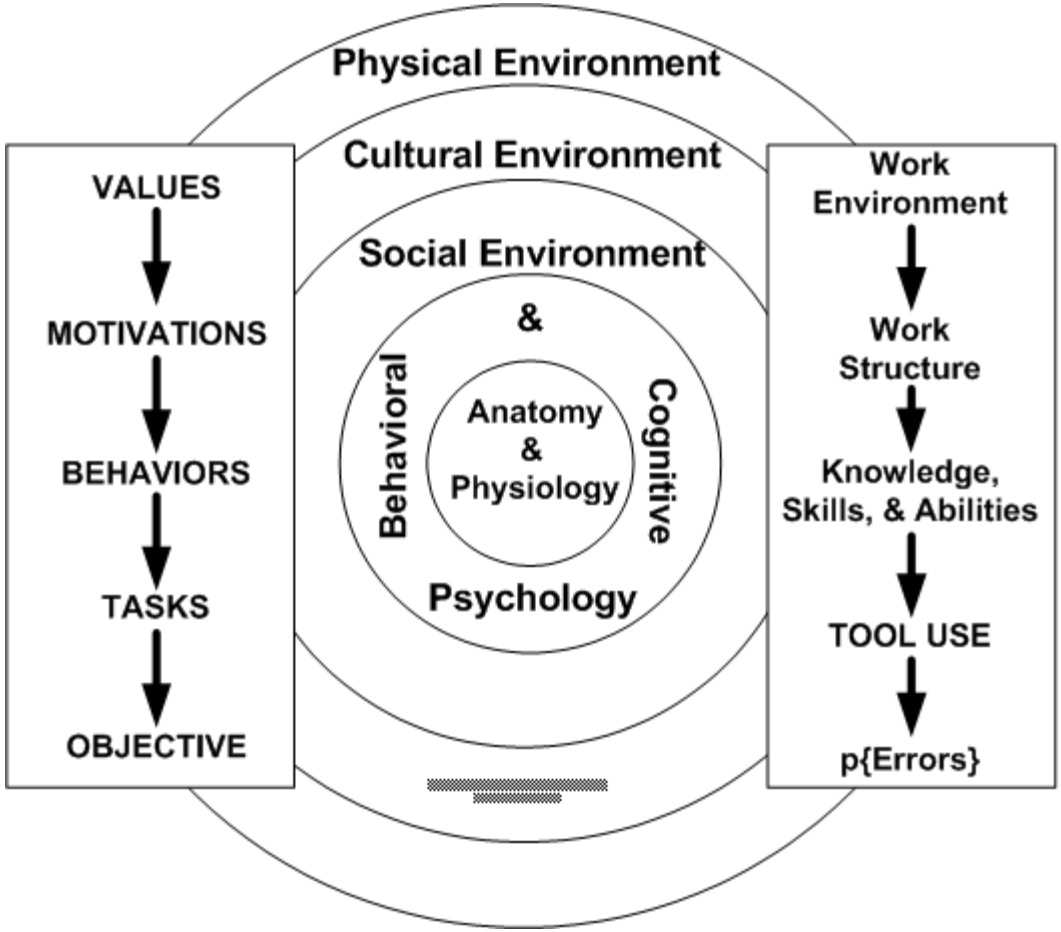
Micro/Macro-Ergonomic Lifecycles



HCSE Common Domains

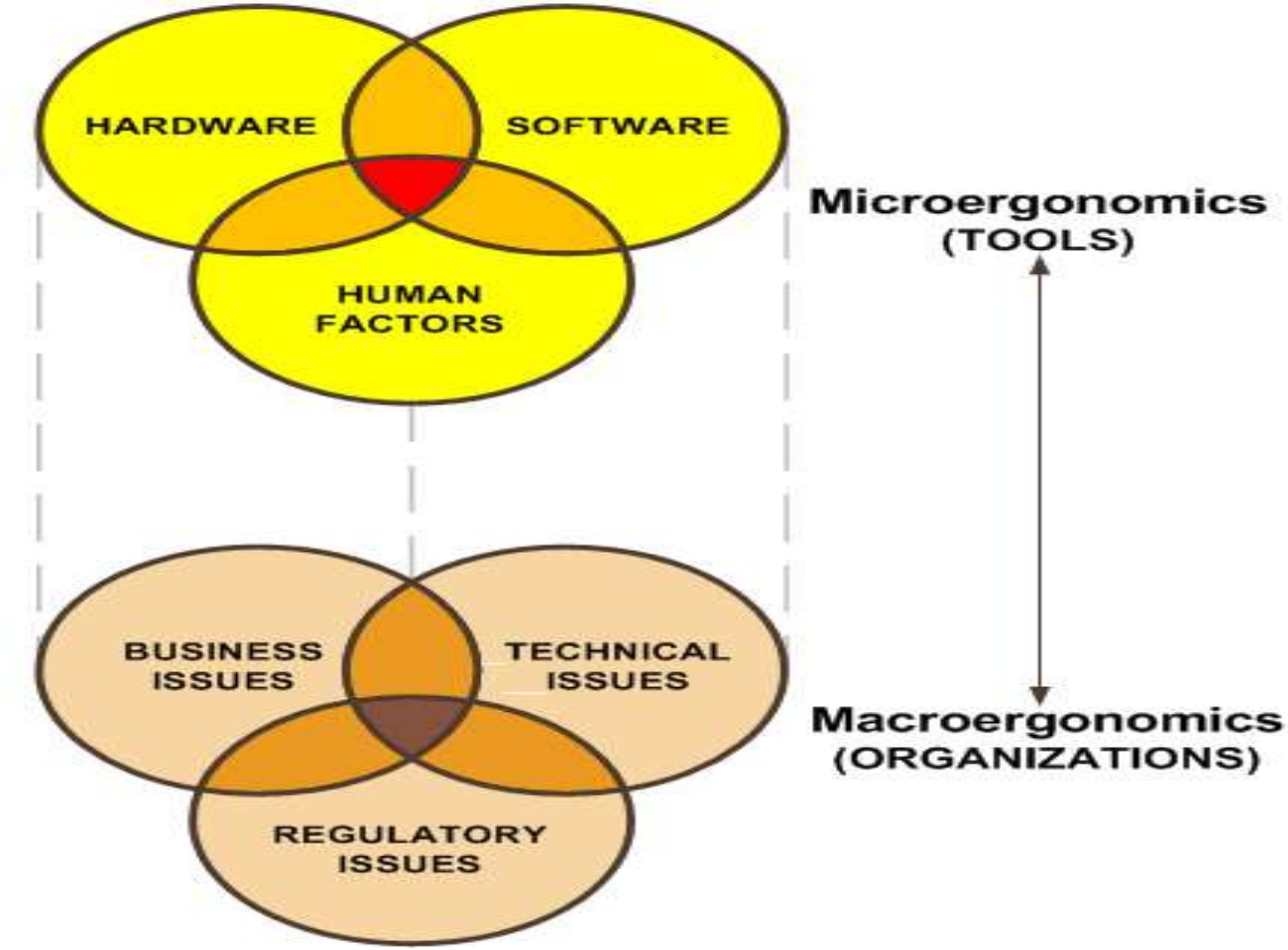
Requirements Engineering	Compliance Engineering	Reliability Engineering
Stakeholder Identification, NWD Assessment & Reconciliation	Identification of Laws, Regulations, & Standards	Defining Minimum Necessary Reliability
Hazard Analyses (Risk Mgmt)	Applicability Assessment	Fault Prevention
Design Input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

Factors for Actors



Operate in complex environment - influences achievements and errors

Error Sources & Interactions



Human-Centered System Complexity