ERGONOMICS & FORENSIC ENGINEERING

GM Samaras, PhD, DSc, PE Samaras & Associates, Inc. Pueblo, CO USA 81005

george@samaras-assoc.com

www.samaras-assoc.com/PublicDocs/NAFE_Denver_2019

OBJECTIVES

- Provide some background on HF&E
- Offer a rubric (algorithm) for identifying HF&E issues in forensic engineering analyses
- Discuss a simple example to demonstrate how the rubric may be used

GOAL

ALL forensic engineers, regardless of discipline, can identify human factors & ergonomics issues related to incidents/accidents.

Some Terminology & Concepts

- **Ergonomics** Continental (European) Term
- Human Factors North American Term
- HF&E all about fitting tools to humans, not humans to tools (has been demonstrated to reduce p[Errors] and increase safety)
- NWDs Needs, Wants, & Desires (of stakeholders)
- Overt Detectable with 1 of 5 senses
- Covert Requires Instrumentation (good example: velocity)
- Socio-Technical System System Consisting of <u>Infrastructure</u> plus <u>Humans</u> – virtually every work system built by humans ...
- FUNDAMENTAL PRINCIPLE: <u>ALL</u> man-made systems have human users: developers, deployers, end-users, & maintenance/disposal persons

Human Factors & Ergonomics (HF&E)

Mike Baldwin / Cornered

6

At its most fundamental, HF&E is about:

Fitting the <u>Tool</u> & the <u>Environment</u> to the <u>User</u>,

NOT

trying to contort the user to fit the tool(s) ... which results in <u>errors</u>

> leading to <u>accidents</u> & injuries.



BAQuin

SOME THEORY

Human(s) Operating with Tools

Anthropometry Biomechanical & Sensory Processes

Human(s) Operating with Tools with Automation

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

Human(s) Operating Within Organizations

Communication & Coordination Conventions & Expectations

Human(s) Operating Within (Sub-)Cultures

Language & Artifacts Beliefs, Customs, Ethics, & Morals Human-Centered System Complexity Copyright © 2006-2014, GM Samaras All Rights Reserved Micro-Ergonomics (Physical Ergonomics)



Meso-Ergonomics (Information Ergonomics)



Macro-Ergonomics (Social Ergonomics)



Mega-Ergonomics (Cultural Ergonomics)



Micro-Ergonomics (Physical Ergonomics)

OVERT FACTORS

Anthropometry

COVERT FACTORS

- Biomechanics
- Sensory Processes
- S-M Integration

Human(s) Operating with Tools

Meso-Ergonomics (Information Ergonomics)

OVERT FACTORS

- Verbal Behaviors
- Non-Verbal Behaviors

COVERT FACTORS

- Affective Behaviors
- Cognitive Behaviors
- Physiological Behaviors

Human(s) Operating with Tools with Automation

Macro-Ergonomics (Social Ergonomics)

OVERT FACTORS

- Communication
- Coordination

COVERT FACTORS

- Conventions
- Expectations

Human(s) Operating within Organizations

Mega-Ergonomics (Cultural Ergonomics)

OVERT FACTORS

- Linguistics
- Artifacts

COVERT FACTORS

- Beliefs
- Customs
- Ethics
- Morals

Human(s) Operating within (Sub-)Cultures

The following three slides form the theoretical basis of the rubric

Error Taxonomy

	ERROR CATEGORY	
ERROR TYPE	SYSTEM USE ERROR	INDIVIDUAL USER ERROR
EXPECTED BEHAVIOR	ACTIVE (KNOWN BUGS)	ROUTINE USE
UNEXPECTED Behavior	LATENT (UNKNOWN BUGS)	NOVEL USE
MISGUIDED Behavior	DRIFT (BEYOND DESIGN ENVELOPE)	MISUSE
MALICIOUS Behavior	SABOTAGE	ABUSE
	LOCUS OF CONTROL: DEVELOPMENT, DEPLOYMENT,& MAINTENANCE ORGANIZATIONS	Locus of Control: Individual Human(s)

Individual UseR Errors



System Use Errors



Virtually guaranteed that a defective product or system can be traced back to a defective risk management process.

Defective risk management process then adversely impacts design control, personnel selection and training, and proper user focus.

Pre & Post Market Risk Management

Iteration Steps	PreMarket Development	PostMarket Vigilance
1	Hazard Identification	Complaint Management
2	Hazard Recognition	Sentinel Event Recognition
3	Hazard Risk Evaluation	Health Hazard Evaluation
4	Risk Control Application	Corrective and Preventive Action
5	Risk Control Verification/Validation	CAPA Verification/Validation

FE HF&E Rubric

- Categorize Humans Involved in Socio-Technical System
- Identify Individual UseR Errors; Determine Type
- Identify System Use Errors; Determine Type
- **Report** HF&E Issue(s)

	ERROR CATEGORY		
ERROR TYPE	SYSTEM USE ERROR	INDIVIDUAL USER ERROR	
EXPECTED BEHAVIOR	ACTIVE (KNOWN BUGS)	ROUTINE USE	
UNEXPECTED Behavior	LATENT (UNKNOWN BUGS)	NOVEL USE	
MISGUIDED Behavior	DRIFT (BEYOND DESIGN ENVELOPE)	MISUSE	
MALICIOUS Behavior	SABOTAGE	ABUSE	
	LOCUS OF CONTROL: DEVELOPMENT, DEPLOYMENT,& MAINTENANCE ORGANIZATIONS	Locus of Control: Individual Human(s)	



Individual UseR **Errors**

- Training Issues?
- Workload Issues?
- Memory Issues?
- **Behavioral Issues?**





IndUseR

Training?

Ν

Y

No Training

Lack of Comprehension

Failure to Apply Training

Physical Workload

System Use Errors

- Control of Design?
- Management of Risk?
- Personnel Selection & Training?
- User Focus?





PRACTICAL EXAMPLE

Fictitious Example

- Modified to disguise actual incident
- CASE:
 - Doc walks into OR
 - Pt. Anaesthetized
 - iPhone battery low
 - Plugs into USB port on front panel of medical equipment system
 - Medical Equipment does not operate
 - Neither Pt. or iPhone seriously injured
 - Surgery cancelled
- In real life, could have been catastrophic event (near HIT!).

Practical Example Continued

- Forensic Engineer Invited to Conduct Analysis by Hospital Management & Report Problems & Putative Solutions
- Investigator Visits OR, Interviews Doc & Staff and Requests Production of Various Documents from:
 - Hospital
 - Equipment Manufacturer
- Follows Rubric
- Report Indicates there were Multiple HF&E Failures and Documented Errors

WHAT WERE FINDINGS IN EXPERT REPORT?

End User

Individual User Error – Unexpected Behavior – Novel Use

- No Training on Use of USB Port
- Easily Seen & Readily Accessible
- High Mental Workload
- Absent-mindedly Execute Repetitive Behavior

Proximate Cause of Failure, but <u>not</u> Root Cause

	-	
ERROR TYPE	SYSTEM USE ERROR	INDIVIDUAL USER ERROR
EXPECTED BEHAVIOR	ACTIVE (KNOWN BUGS)	ROUTINE USE
UNEXPECTED Behavior	LATENT (UNKNOWN BUGS)	Novel Use
MISGUIDED Behavior	DRIFT (BEYOND DESIGN ENVELOPE)	MISUSE
MALICIOUS Behavior	SABOTAGE	ABUSE
	LOCUS OF CONTROL: DEVELOPMENT, DEPLOYMENT,& MAINTENANCE ORGANIZATIONS	Locus of Control: INDIVIDUAL HUMAN(S)

ERROR CATEGORY

Hospital Personnel

- System Use Error Unexpected Behavior Latent Defect
- Biomed Techs Aware of Port Use, but not Aware of Hazard; did not share with Risk Manager
- One of Surgical Techs had made mistake, but <u>not reported</u> it; had family emergency night before and was sleep-deprived that day
- Reduced ability <u>equivalent</u> to elevated mental & physical workload
- Did not notice Doc plugging in; was focused on her own tasks
- Indicative of Macro-Ergonomic Flaws:
 - Defective Communications & Coordination;
 - Incorrect Conventions & Expectations
- Intermediate & Enabling Cause, but <u>not</u> Root Cause

		ERROR CATEGORT	
	ERROR TYPE	SYSTEM USE ERROR	INDIVIDUAL USER ERROR
	EXPECTED BEHAVIOR	ACTIVE (KNOWN BUGS)	ROUTINE USE
	UNEXPECTED Behavior	LATENT (UNKNOWN BUGS)	NOVEL USE
	MISGUIDED Behavior	DRIFT (BEYOND DESIGN ENVELOPE)	MISUSE
	MALICIOUS Behavior	SABOTAGE	ABUSE
ause		LOCUS OF CONTROL: DEVELOPMENT, DEPLOYMENT,& MAINTENANCE ORGANIZATIONS	Locus of Control: Individual Human(s)

Manufacturer Personnel

- System User Error Expected Use Active Defect
- Known "Feature", but not Recognized as <u>Use Hazard</u>
- No User Focus (Foreseeable Users, NWDs, Use Hazards)
- Document Examination showed Defective Risk Analysis
 - Detectability falsely reduced risk priority
 - No risk controls except for service personnel
 - No label comprehension & usability validation
- Postmarket complaints received, but not recognized as Use Hazar
- Generic SOPs and Lack of Employee Training Exacerbated other failures

Defective Manufacturer Management recognized as <u>Root Cause</u>

		ERROR CATEGORY		
	ERROR TYPE	SYSTEM USE ERROR	INDIVIDUAL USER ERROR	
	EXPECTED BEHAVIOR	ACTIVE (KNOWN BUGS)	ROUTINE USE	
	UNEXPECTED Behavior	LATENT (UNKNOWN BUGS)	NOVEL USE	
	MISGUIDED Behavior	DRIFT (BEYOND DESIGN ENVELOPE)	MISUSE	
	MALICIOUS Behavior	SABOTAGE	ABUSE	
lazard		LOCUS OF CONTROL: DEVELOPMENT, DEPLOYMENT,& MAINTENANCE ORGANIZATIONS	Locus of Control: Individual Human(s)	

QUESTIONS??



KNOWLEDGE QUESTION

Learning Question

An Endoscope (a tube put inside body to allow docs to see without cutting you open) suspected of transmitting infections because it is not being adequately cleaned between uses.

The folks that do cleaning and disinfecting (reprocessing) are:

- lower wage, GED+ individuals,
- under considerable time pressure, and
- work in poor environmental conditions.



Identify Candidate HF&E Issues

System **USE** Errors (Remember: Who design & deployed)

Design Defect(s)

- Risk Management Flaw(s)
- Personnel Selection/Training

User Focus

Individual **UseR** Errors (Remember: Who are end users)

Training

- Workload
- □ Memory
- Behaviors

EXTRAS

Ergonomics	Factor	Example(s)	
Micro-	Overt:	Static size & fit of an individual (range of adjustment of operating table)	
	Covert:	Biomechanical – weight & balance of individual surgical tools Sensory – multiple alarms interfering with high priority alarm recognition S-M Integration – hand/eye coordination fidelity	
Meso-	Overt:	Verbal/Non-verbal info mgmt. behaviors – verbalization & trackball ops while usin computerized system	١g
	Covert:	Affective – frustration with simultaneous alarms Cognitive – difficulty recognizing highest priority alarm Physiological - ↑ HR/RR due to time pressure & alarm recognition issues	
Macro-	Overt:	Communication – 2 nurses verifying drug & dosage setting for device Coordination – equipment buyer not communicating with nurse end users	
	Covert:	Conventions – buyer ignores nurse users' preference; buyer uses preferred vendo Expectations – buyer expects clinicians will "safely & effectively" use any device	ors
Mega-	Overt:	Language – clinicians & engineers do not use/understand same language Artifacts – devices familiar to clinicians unfamiliar to engineers & vice-versa	
	Covert:	Shared values, such as beliefs, customs, ethics, & morals, differ between cliniciar and others (engineer, legal, business, etc.)	ns
		www.samaras-assoc.com/PublicDocs/NAFE_Denver_2019 32	

Additional Definitions

- MISATTRIBUTION attributing an event to something with which it really has no connection or association
- BIAS tendency, inclination, or prejudice toward or against something or someone
- **SUGGESTIBILITY** acceptance of false suggestions made by others
- PERSISTENCE inability to forget unwanted recollections (usually traumatic)
- **MISORDERING** of tasks means doing them out of sequence
- DESIGN VERIFICATION experimentally confirming the existence of a design attribute
- DESIGN VALIDATION experimentally confirming the complete system meets the preselected user needs, wants, & desires for the intended use in the intended user environment
- **RISK** uncertainty of deviation from an expected or predicted outcome