



INCOSE Healthcare Working Group Webinar - March 23, 2018
Leveraging 21st Century SE Concepts, Principles, and Practices to Achieve User, Healthcare Services, and Medical Device Development Success
Presenter – Charles Wasson, ESEP



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**Leveraging 21st Century
SE Concepts, Principles, and Practices
to Achieve User, Healthcare Services, and
Medical Device Development Success**

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In Systems Engineering & Product Development

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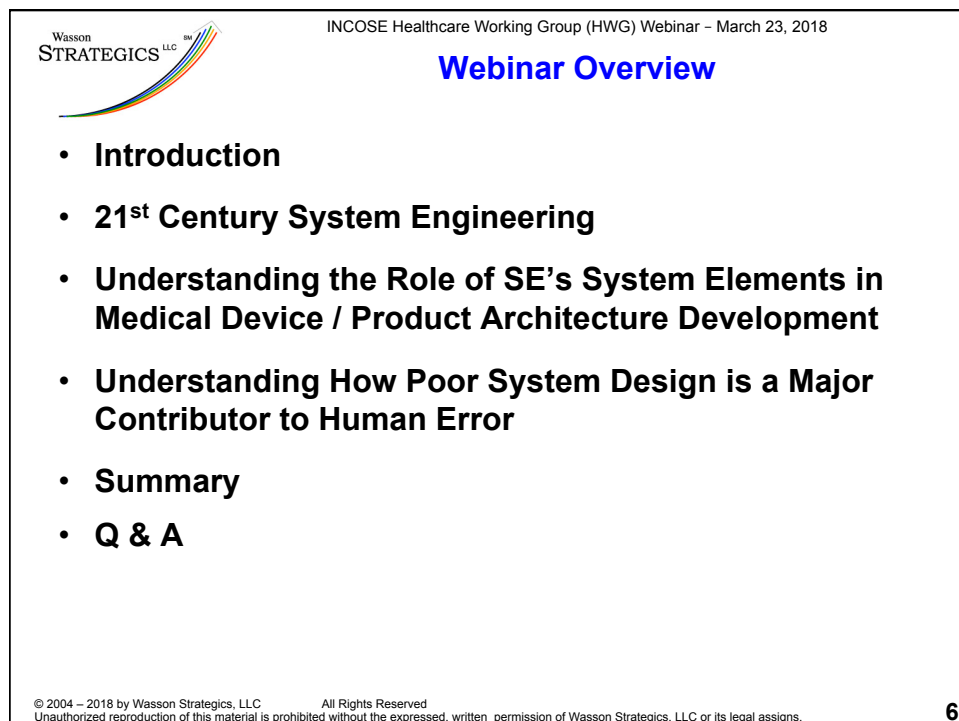
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- References to these organizations are intended to build on the contents of the INCOSE Jan. 12, 2018 HWG webinar presentation to illustrate how 21st Systems Engineering might have been or can be applied to healthcare situations and medical products development.
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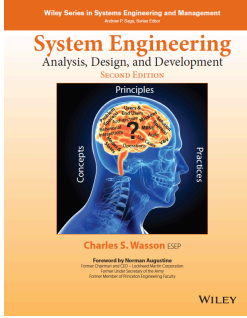
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21st Century Systems Engineering

Objective
*Linking SE Concepts to Healthcare Services
 and Medical Products Development*

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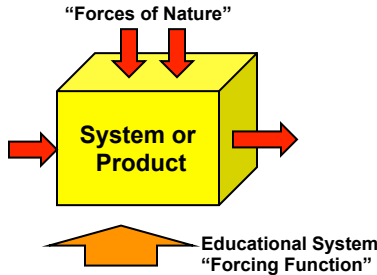
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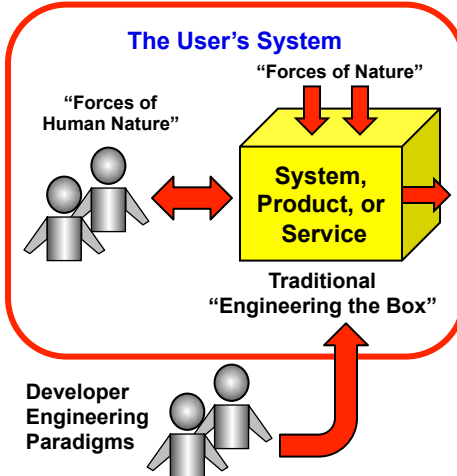
21st Century SE – What's Different?

**Traditional
“Engineering the Box”**



Engineering
 “[T]he profession in which knowledge of the mathematical and natural sciences gained by study, experience, and practice is applied with judgment to develop ways to utilize economically **the materials and forces of nature** for the benefit of mankind.” [Prados (ABET), 2007]

**21st Century
“Engineering the System”**



Wasson, Charles S. (2016) *System Engineering Analysis, Design, and Development: Concepts, Principles, and Practices*, p. 9, New York: John Wiley & Sons, Inc.

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21st Century Systems Thinking


**Traditional
Engineering the “Box”**



<https://tse4.mm.bing.net/th?id=OIP.IN6aNDLkzVIRVLhrtwVLpAAAA&w=222&h=171&c=7&o=5&pid=1.7>

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**21 Century
Engineering the “System”**



Source: Dietz, Doug (2018), INCOSE Healthcare Working Group (HWG) Webinar, Jan. 12, 2018, Milwaukee, WI: GE Healthcare.

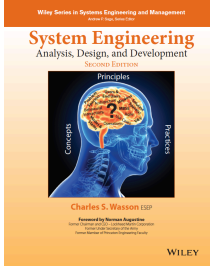
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“System” Definition



- **INCOSE System Definition¹**
 - An integrated set of system elements, subsystems, or assemblies that accomplish an objective.
- **Wasson System Definition²**
 - An integrated set of interoperable elements or entities, each with specified and bounded capabilities, configured in various combinations that enable specific behaviors to emerge for **Command and Control (C2) by Users to achieve performance-based mission outcomes in a prescribed operating environment with a probability of success.**

Sources:

1. INCOSE (2015), *Systems Engineering Handbook, (SEH v4.0)*, Appendix C Terms and Definitions, p.265, San Diego, CA: International Council on Systems Engineering (INCOSE).
2. Wasson, Charles S. (2016) *System Engineering Analysis, Design, and Development: Concepts, Principles, and Practices*, p. 2, New York: John Wiley & Sons, Inc.

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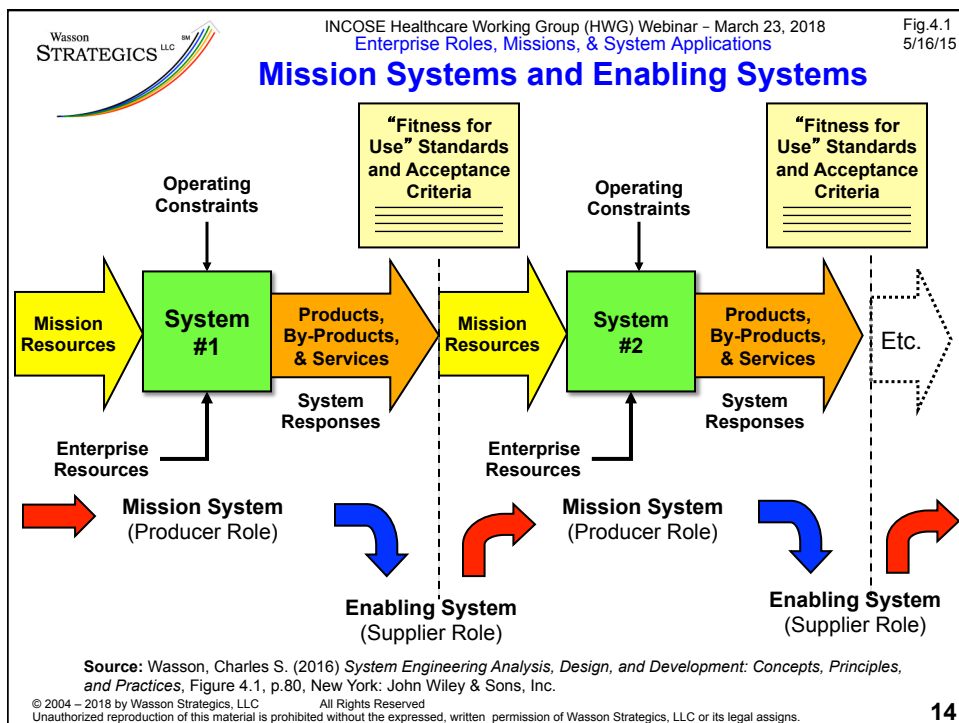
Duality of System User & End User Roles


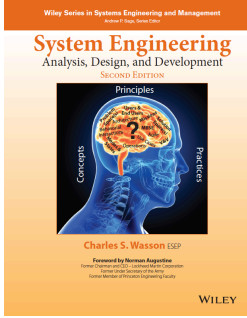
- System User Role**
 - An individual, organization, or Enterprise that **operates, commands and controls (C2) a system or provides inputs**—data, consumables an expendables, raw materials, or pre-processed materials.
 - As a result of system usage under their control, Users control system outputs to provide results such as information, data, reports, and End Users to perform their tasks or make decisions. **Users may require proficiency training and possibly certification**
- System End User Role**
 - An individual, organization, or Enterprise that **derives benefits** directly or indirectly from a system and/or its products, services, or by-products.
 - End Users may or may not require training for reading, interpreting work products / results.**

*Source: Wasson, Charles S. (2016) *System Engineering Analysis, Design, and Development: Concepts, Principles, and Practices*, p. 84, New York: John Wiley & Sons, Inc.

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Webinar Topic #1

How Agile Development methods coupled with Use Cases (UCs) and Scenarios enable a better identification, understanding, definition of stakeholder operational needs, capabilities, and requirements.

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**The System's Operating Environment ...
 More than Temperature, Humidity, Shock, etc.**



Our BIG challenge

P.O.V.

We met...
 Scared families trying not to fall apart during a hospital visit.

We were amazed to realize...
 They have to **sedate 80% of the children** so they don't panic and can hold still for their scan.

conversation in the car ride home.

How do we address this?

Patient Anxiety Curve

Arrive, Trip, Imaging procedure, This

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Agile Application - Author's Perspective*

Radical Collaboration
Bruce from Disney: 20 Customers / 7 GE Employees
Child Life Specialists, Family Advisory Board

Build to Learn
"The person in the meeting with a prototype WINS" – David Kelly, IDEO

Agile Development Sprint Work Cycle

* May or may not be GE's perspective or intent.

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Sources:

1. Dietz, Doug (2018), INCOSE Healthcare Working Group (HWG) Webinar, Jan. 12, 2018, Milwaukee, WI: GE Healthcare.
2. Wasson, Charles S. (2016) *System Engineering Analysis, Design, and Development: Concepts, Principles, and Practices*, Figure 15.9, p.335, New York: John Wiley & Sons.

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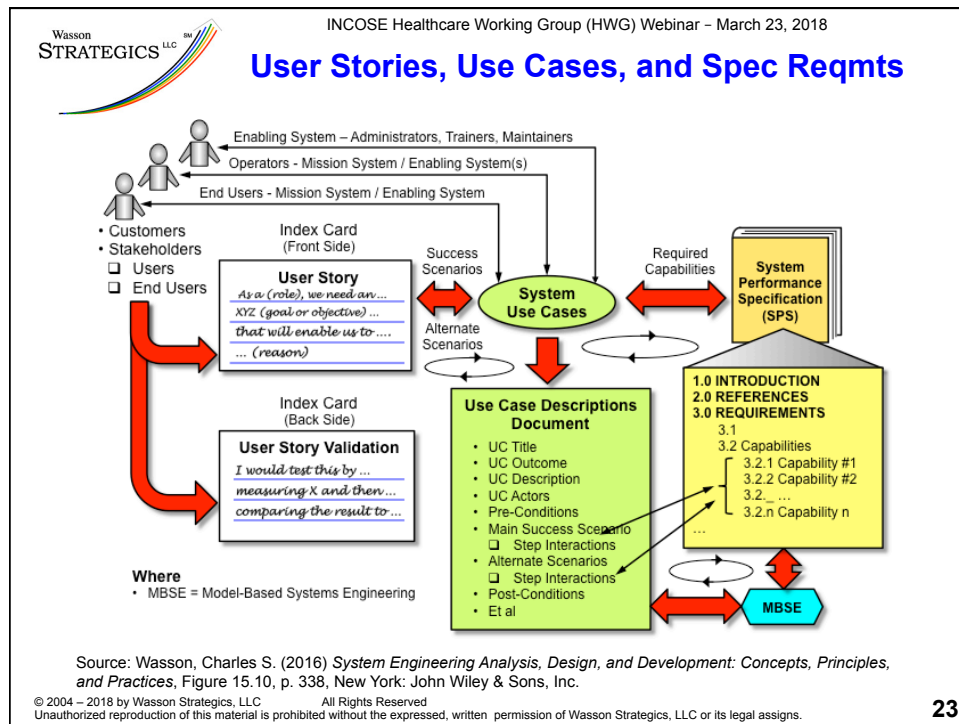
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Operating Environment Overview

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Webinar Topic #2

Understanding the relevance, criticality, and application of the SE System Elements to Reason's (Swiss Cheese) Accident Trajectory Model for Healthcare and Medical Products system, product, and services development.

System Engineering
Analysis, Design, and Development
Second Edition
Principles
Charles S. Wasson ESEP
WILEY

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INCOSE's Definition of System Elements

System
An integrated set of elements, sub-systems, or assemblies that accomplish a defined objective. These elements include products (hardware, software, firmware), processes, people, information, techniques, facilities, services, and other support elements (INCOSE)
A combination of interacting elements organized to achieve one or more stated purposes (ISO/IEC/IEEE 15288)

System element
Member of a set of elements that constitutes a system

Source: INCOSE (2015), *Systems Engineering Handbook, (SEHv4.0)*, Appendix C Terms and Definitions, p.265, San Diego, CA: International Council on Systems Engineering (INCOSE).

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Systems, Engineering, & Systems Engineering

System Elements

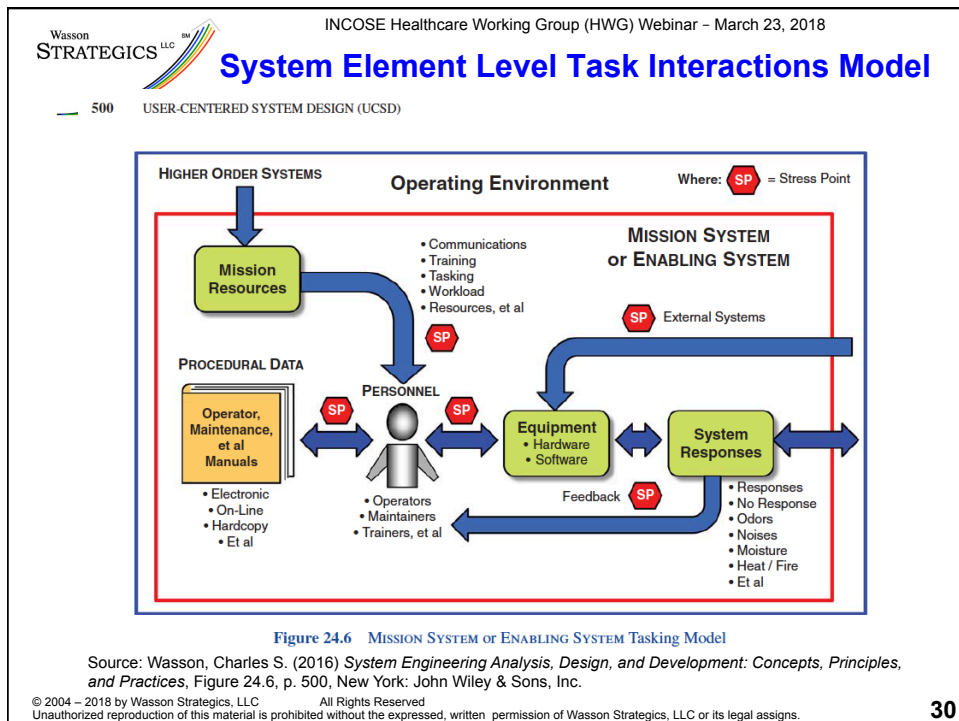
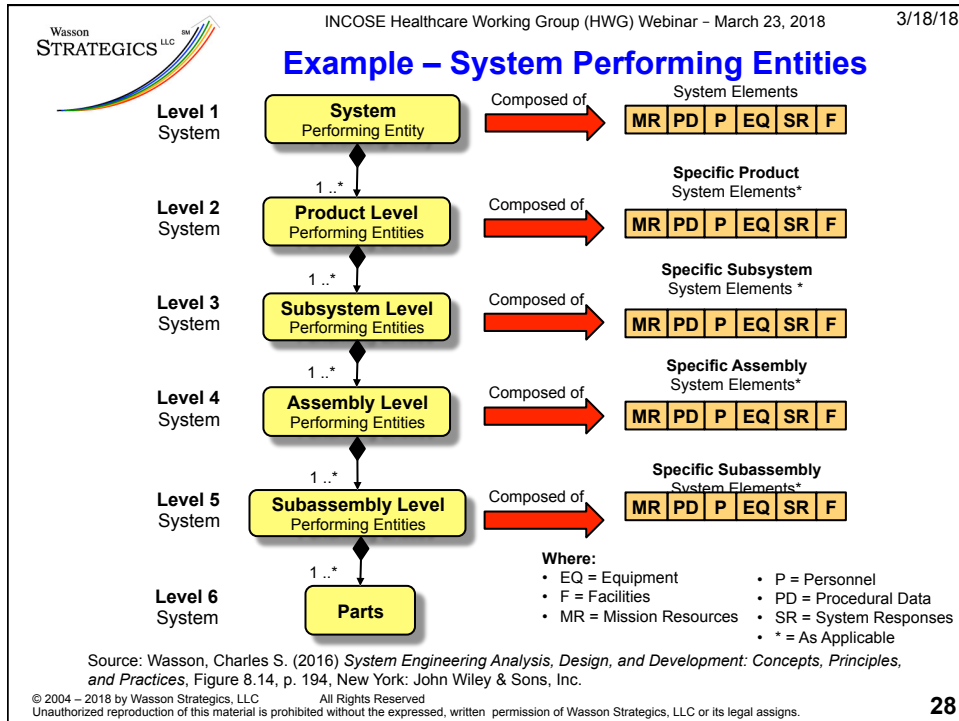
- **System Element**
 - A label applied to classes of entities that comprise a System of Interest's (SOI's) Mission System and Enabling System(s), Higher Order Systems, or Physical Environment domains.
- **System Elements consist of:**
 - Personnel
 - Equipment
 - Mission Resources
 - Procedural Data
 - System Responses
 - Facilities

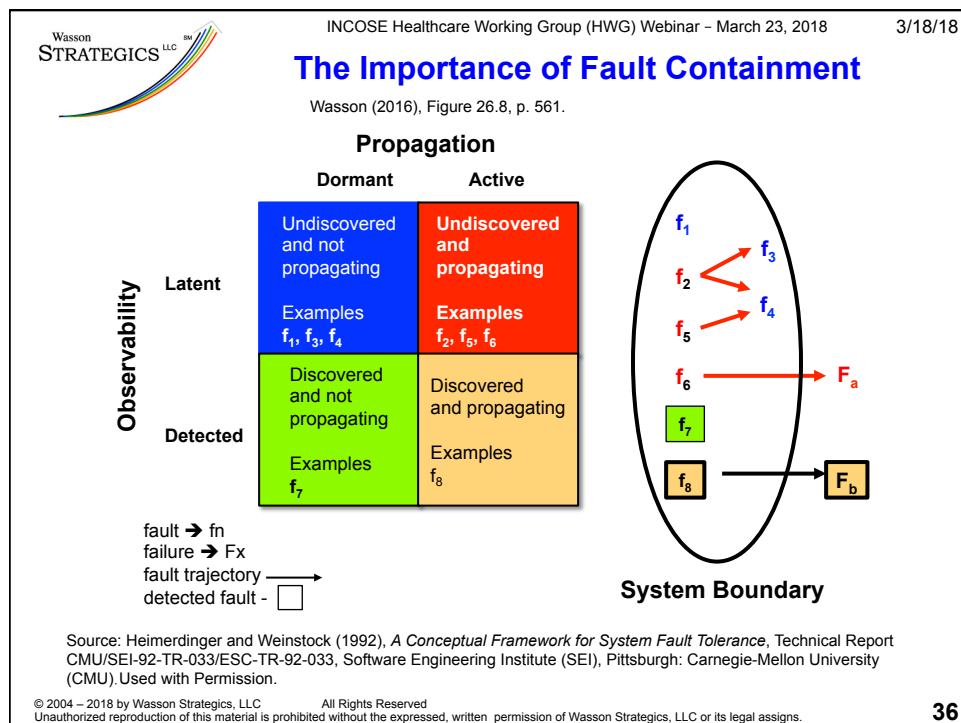
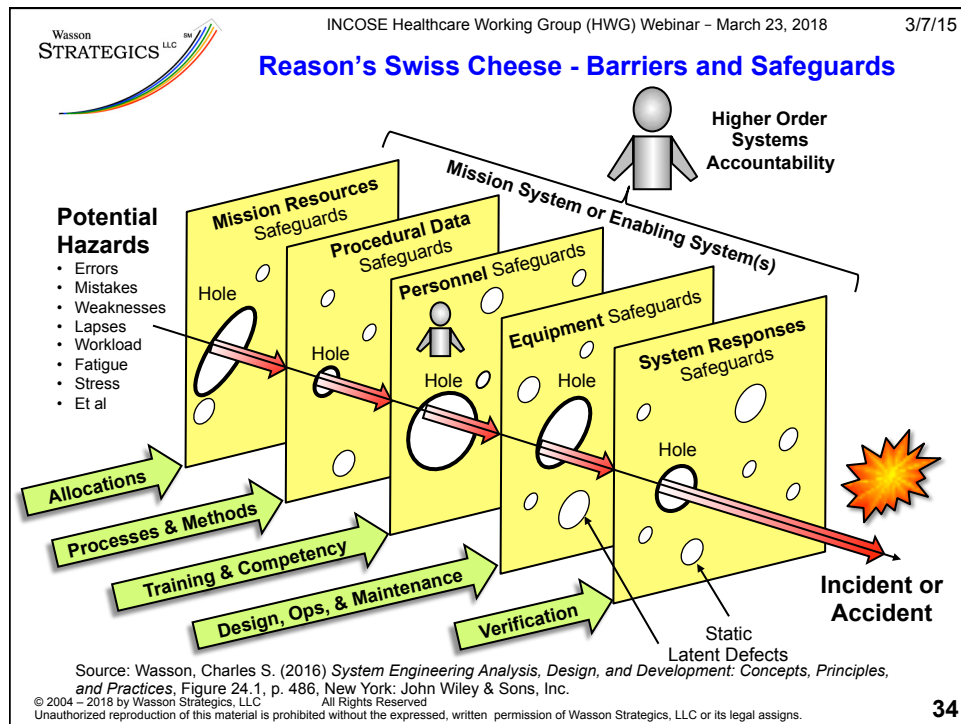
Sources:


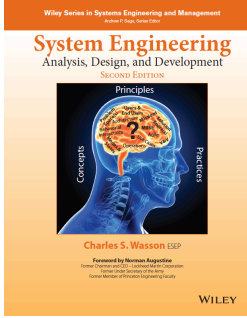
1. Wasson, Charles S. (2016) *System Engineering Analysis, Design, and Development: Concepts, Principles, and Practices*, p. 52, New York: John Wiley & Sons, Inc.
2. Photo - https://almanac.upenn.edu/archive/volumes/v58/n16/images_n16/ryan-vet.jpg

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Webinar Topic #3

Understanding how poor System Design
 influences operator actions that may lead
 to system, product, or service failures
 that are often erroneously blamed on
 “human error” as the “single root cause.”

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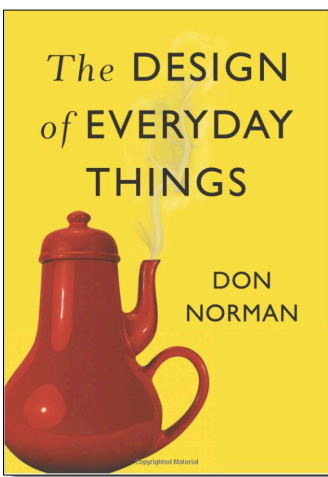
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Usability – Human “Fitness for Use”



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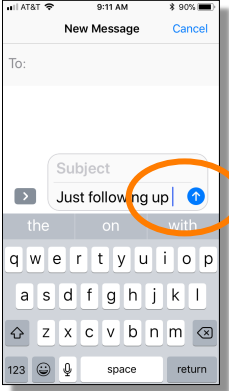
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Poor System Design – Simple Example

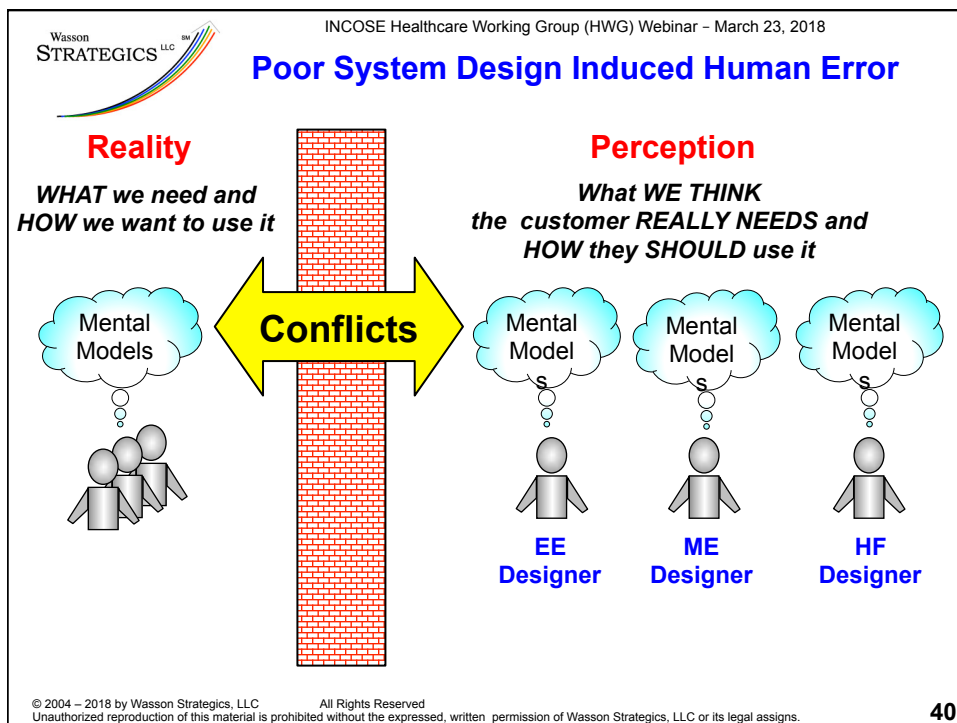
In sending a text message, have you ever reached the end of a line, decided to manually replace the previous word, and inadvertently touched the SEND button?

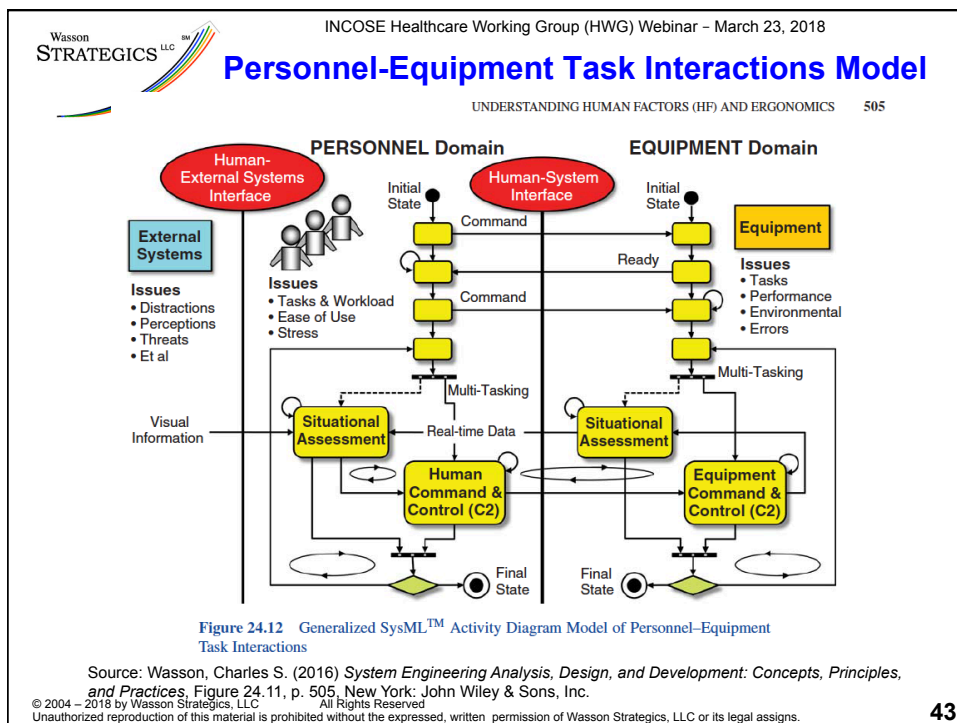
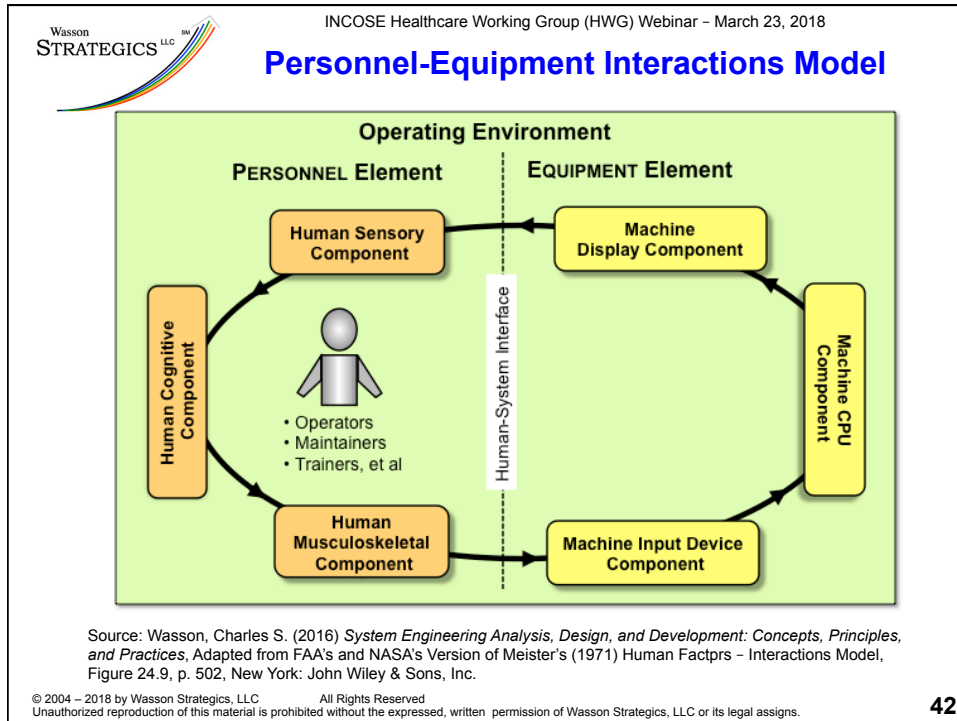


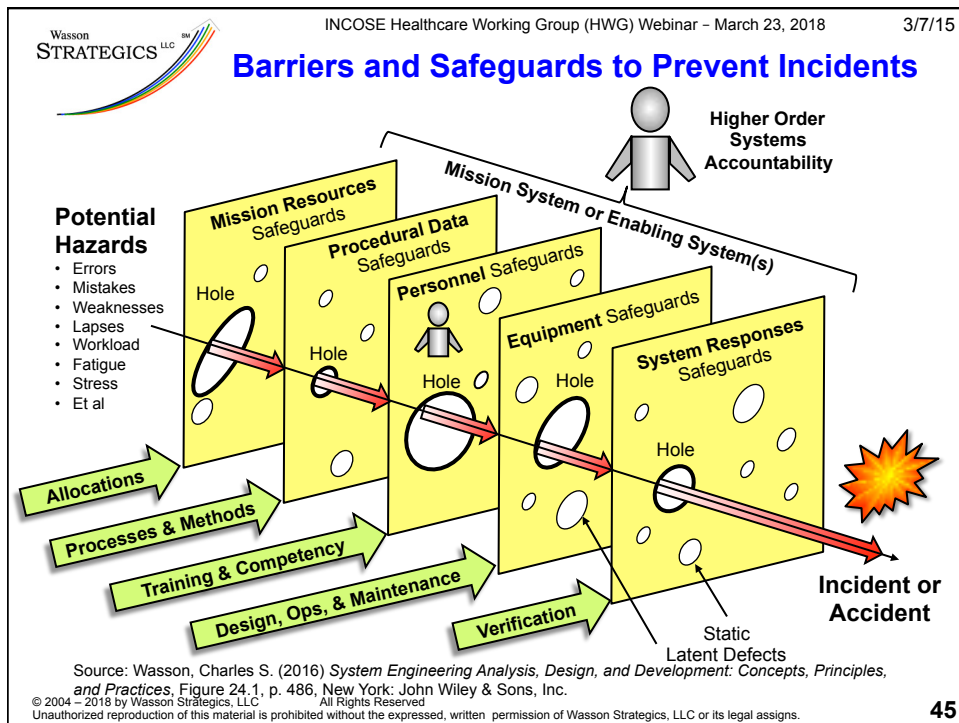
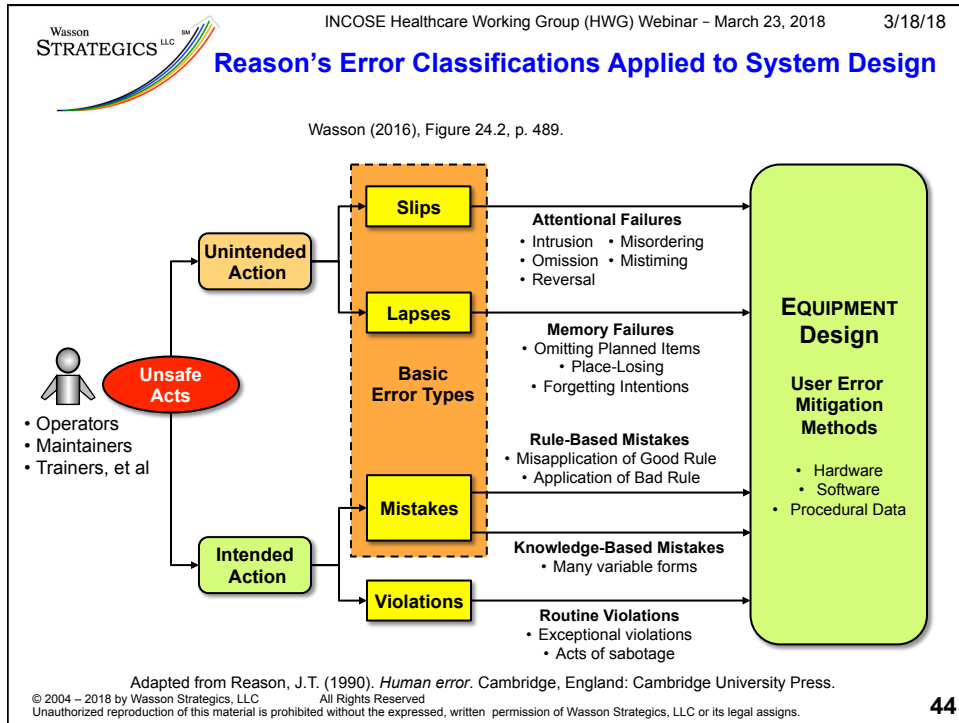
Imagine being half way to Mars and this happens leading to catastrophic event or during surgery with a medical device?

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Summary

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21st Century Healthcare

**Traditional
Engineering the “Box”**



**21 Century
Engineering the “System”**



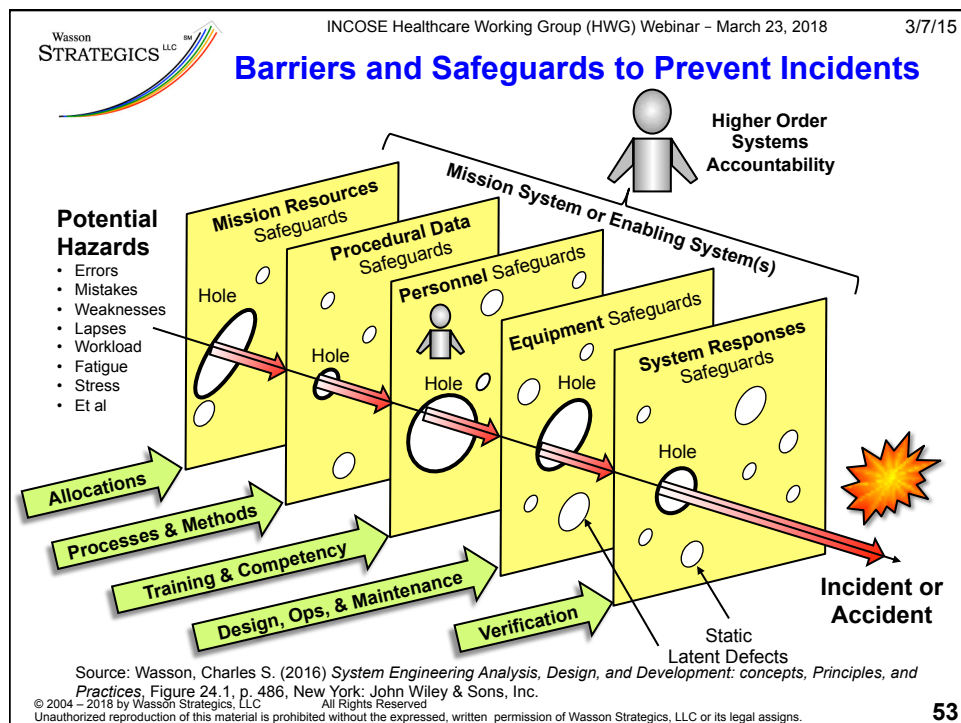
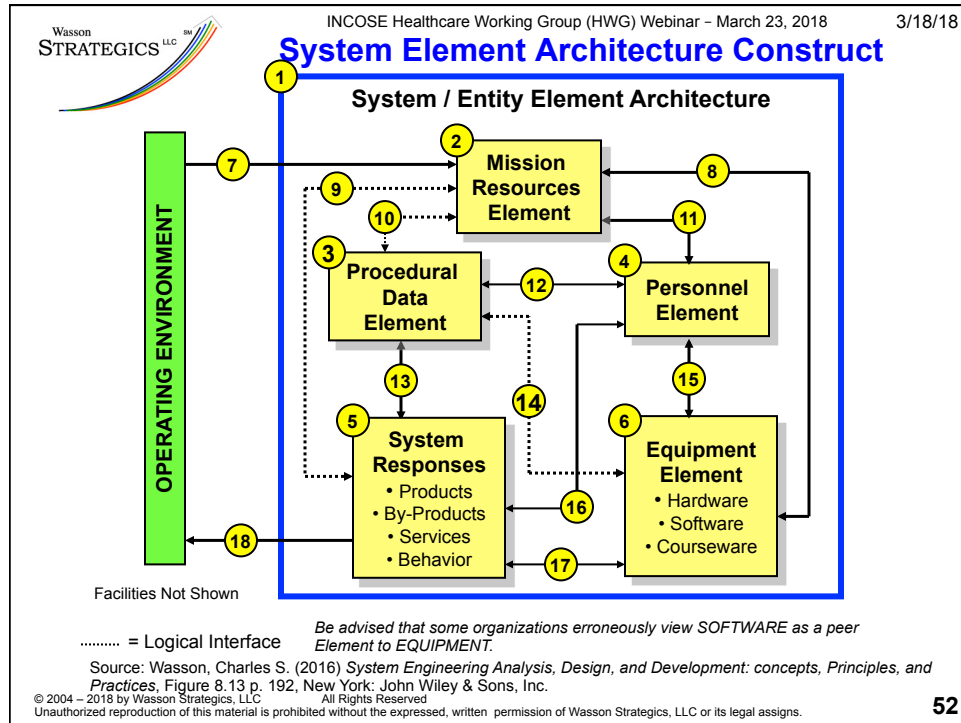
<https://tse4.mm.bing.net/th?id=OIP.IN6aNDLkzVIRVLhrtwVLPAAAA&w=222&h=171&c=7&o=5&pid=1.7>



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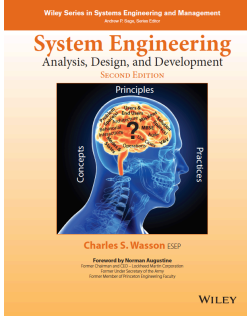


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Questions & Answers



Thank You!

***... for the invitation to present today's
INCOSE Healthcare Working Group
Webinar!***

Charles Wasson
March 23, 2018

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