LESSONS LEARNED FROM STPA APPLICATIONS

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System Safety experiences with systems including products and services: Medical Device, Healthcare Services, Power Generation, Fire Fighting PPE and control systems, Infrastructure, Manual and Automated Manufacturing, Visual Inspection, Automotive, Aerospace

Provide extensive systems consulting experience. Founder of System Design and Strategy Ltd, previous experience at Accenture and Cambridge Consultants. Experience providing systems consulting and training to a wide range of industry sectors worldwide.


Education and research background. Chemical Engineering Bachelors (Cornell University), System Design and Management Masters (Massachusetts Institute of Technology), dissertation on System Safety Approaches Applied to Healthcare Adverse Events. Experience in Genetics, Healthcare and Systems Research.


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STPA HIGHLIGHTS

- Master thesis, MIT; Dr. Nancy Leveson
  - Application of CAST to Healthcare Adverse Events (2014)

- System responsibilities as director level leader and as consultant:
  - Director for System Engineering and responsible owner for Risk Management, Class I and II medical device which included STPA and other methods
  - STPA trainer, facilitator
  - External reviewer of system safety approaches and safety critical system designs
  - Applied STPA to identify business development opportunities

- Application in a wide of Systems:
  - Medical Device (Class I and Class II), Biomedical Reactor Design, Healthcare Services, Power Generation and Storage, Fire Fighting PPE and control systems, Infrastructure, Manual and Automated Manufacturing, Visual Inspection, Automotive, Aerospace
LESSONS LEARNED HIGHLIGHTS FROM MY PRACTITIONER EXPERIENCE WITH APPLYING STPA OVER THE LAST TEN YEARS

- Apply STPA early iteratively throughout design process to maximize benefits
- Process aids developing a consistent mental model across the design team
- Successful approaches are a “team sport”
- Common design challenges uncovered: underdeveloped feedback loops and changes in control structure
- Manage expectations and value diversity
FIRST APPLICATIONS OF STPA OFTEN OCCUR LATE IN A PROGRAM SCHEDULE

Common reasons:

External consultation:
- Unresolved concern(s) at entry to formal testing
- First time applying STPA internally falters

Internal application:
- STPA applied when design FMEA’s sessions are scheduled

Common challenges that result:
- Design “freeze” leads to high resistance to change (launch date inertia)
- Viewed as documentation exercise for a regulatory filing, not part of design
- Time with designers may be limited
- “Blame culture” common when late changes realised

<table>
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<th>Phase when error is detected and fixed</th>
<th>Cost to Fix</th>
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<td>x1 (reference)</td>
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<tr>
<td>Design</td>
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<tr>
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INCOSE UK Z3 Guide
APPLY STPA EARLY AND ITERATIVELY THROUGHOUT DESIGN PROCESS TO MAXIMIZE BENEFIT

Benefits:

- Can allow a core team to become familiar and practiced with the method
- Hierarchical Control Diagrams can be less challenging to define at system level
- Design tool that enables safety driven design

Common pitfalls to avoid

- Viewed as a preliminary hazard analysis and not maintained as design changes
- Schedule does not account for time needed
- Discussions but not documented
- Viewed as time based activity; has been “completed” therefore “sufficient”
- Focus on time / cost savings leads to false expectations as “silver bullet”
Develop and discuss hierarchical control structure
- Develops the mental model within the team
- Often prompts development of key system level documentation such as
  - Concept of Operations
  - Concept of Maintenance
  - Mode Transitions
  - Alternatives
  - Rationale for design decisions

Why would a user do that?

Why have you done it that way?

How often does that occur?

Would that always occur?

How would they know that occurred?
COMMON DESIGN CHALLENGES UNCOVERED: UNDERDEVELOPED FEEDBACK LOOPS AND CHANGES IN CONTROL STRUCTURE

- Feedback loops often underdeveloped
- Mode Transitions are often challenging
  - Inconsistent mental models across team
  - Incorrect assumptions
  - Missing Feedback
- Hierarchical control changes
  - Between design, test, deployment
  - Related to alternative or past operator experience
  - Over time
MANAGE EXPECTATIONS AND VALUE DIVERSITY

- Systems thinking 101
  - Diverse team, different perspectives

- Diversity in many forms e.g.
  - People
  - Approaches

- Diversity can require effort
- Manage unrealistic expectations
  - “Silver bullet”
  - “Single approach expected to be better, faster, and cheaper”
  - Conducted by “expert” as a solo activity

- Uncovering issues late can be uncomfortable
- Early discoveries can be forgotten (document as you go)
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