INCOSE

System Impact Analysis

A Systems Engineering Best Practice for Change Management

Agenda

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- State of the Practice & Techniques
- SIA Lifecycle
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Background

When Change Happens

- Unexpected complications often lurk below the surface of technical changes to a complex system
  - Examples:
    - Major: Y2K Problem
    - Minor: Change text of error message in a foreign language.
- Implications to all parts of the system and/or system as a whole not understood
- Causes “Surprises”
  - Rework
  - Schedule delay
  - Wasted work that could have been avoided
  - Money down the drain

Background

- Need to understand implications of the change
- Understand elements of the system affected/impacted
- Accurately estimate the work required for the change
- Make informed decisions that maximize business value and minimize negative impact.
- A common change definition, basis and roadmap for teams to implement changes and submit them to regulatory bodies.

System Impact Analysis Framework

System Impact Analysis is a systems engineering framework and best practice to systemically and systematically identify, analyze, estimate and implement impact of a significant technical change that ripples across an existing, complex system.

Change Proposal Phase:

- Holistic understanding of implications of the change, identifies affected system elements and analyzes impact.

Change Approval/Reject Phase:

- Enables accurate estimation and technical assessment to make informed business decisions

Implementation Phase:

- Provides a common definition, roadmap and basis to effectively drive implementation of the change across the system.

Context of Use

SIA Use Cases:

- New or modified feature/function to an existing system
- Creating a variant product based on an existing one.
- Continuation Engineering Change

Focus on impact views at the system level:

- Functional Impacts that span across system elements
- Architectural Impacts, Interactions, Testing
- Attributes that span across system (Performance, Safety, Security,.)
- Impact across cross-functional areas (Regulatory, Manufacturing…)

State of the Practice

- Determination of system impacts typically done by system engineer types in their heads.
- Not part of formal systems engineering training.
- Fair amount of research and adoption in Software Change Impact Analysis, Techniques and Tools.
  - Vertical focus analyzing control & data dependencies and ripples.
  - Software Change Impact Analysis – Bohner & Arnold
  - Wikipedia Change_impact_analysis
  - Software Requirements – Karl Weigers (focus on sw reqts. driven impact, effort estimation)

State of the Practice - Techniques

Techniques at the SW level

- Traceability Analysis
  - Requirements <-> design <-> code <-> tests
  - Use of tools for traceability analysis.

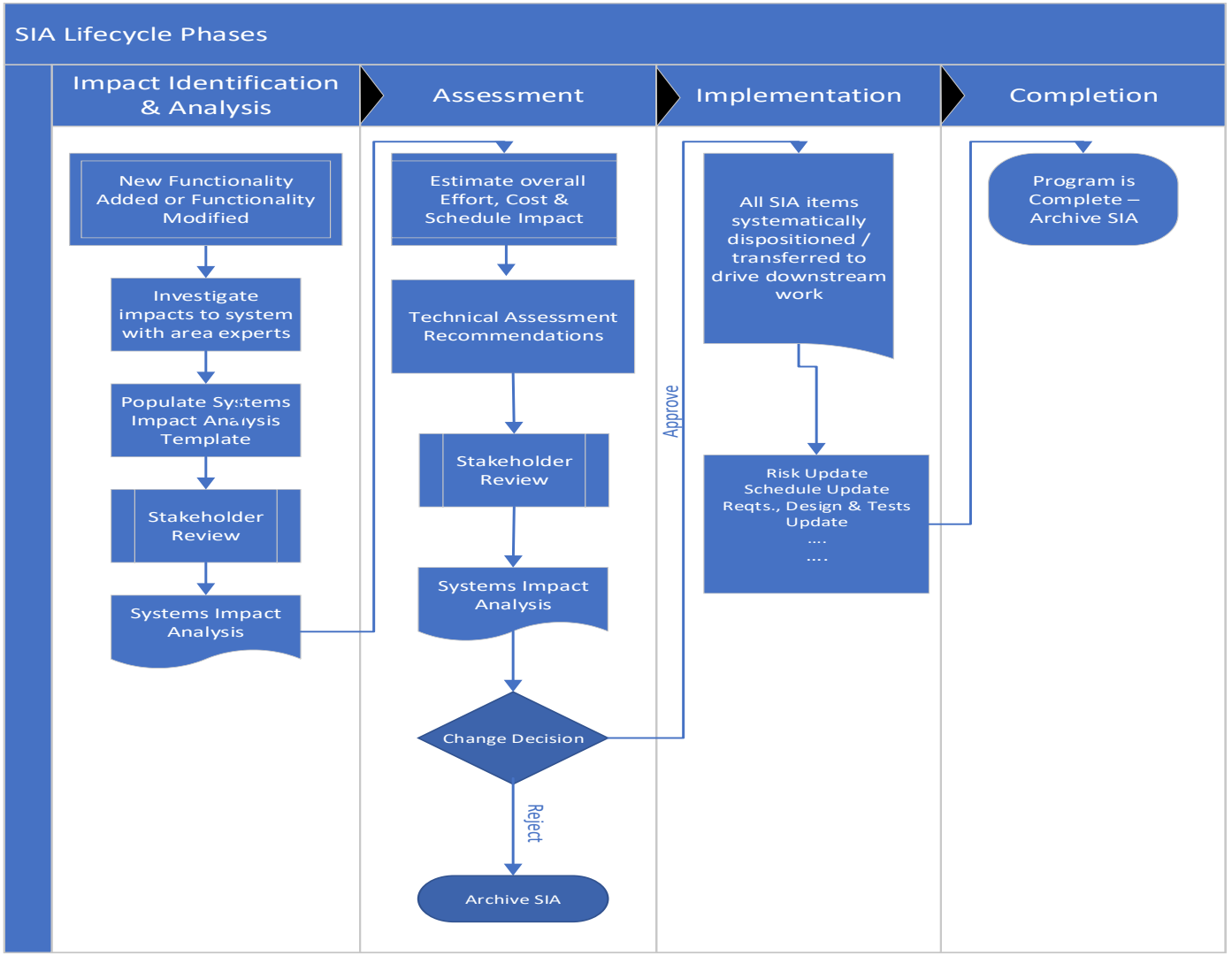
- Dependency Analysis
  - Examine dependency relationships within program space. Data dependencies, Control dependencies etc
  - Program Slicing techniques
  - Use of tools for dependency analysis

State of the Practice - Techniques

Techniques at the System level

- Use of multiple views similar to architecture
- Inter-dependency analysis (use available info / tool support)
- Traceability Analysis (use available info / tool support)
- Experiential

SIA Lifecycle



Systems Impact Analysis Framework Sections

Section	Description
Description & Rationale	Common high-level understanding of change
Interactions with Other Features	Table of all HW/SW/FW features and any possible interactions
Architecture & Overall System Impact	Functional block diagram of system with highlighted changes
Impact to Specific Subsystems	Changes that need to be made to each subsystem to support change
Testing	Testing that can be re-used, new tests that need to be created
System Attribute Impact	Changes to attributes that span across system- Performance, Safety, Security, etc.
Applicability/Future Use	Product configuration, compatibility assessment
Clinical/Regulatory	Regulatory requirements that are impacted by the change
Foreign Countries	Any changes/differences between foreign countries
Battery Life Impact	Evaluation of battery impact due to change
Parameter Management	Identification of new/modified parameters as a part of change
Backwards Compatibility Analysis	Ability to operate with fielded products
Technical Risk	Precursor to formal risk register / documentation
Technical Unknowns	What is not known about change that still needs investigation

SIA Section: Description

High-Level description of the changes to be made.

- Describe the change on the system and how it would behave. If there are similar features/functions, indicate those similarities. Explain overall how it would fit into the existing system.
- This is more than re-iteration of the change in an initial change request.
- This is also where assumptions should be captured
  - At this stage of development, there will be several assumptions that need to be made to provide a general overview of the impact to the system. List out technical assumptions being made for the Systems Impact Analysis.

Rationale

- Rationale for why this change is needed
  - Understand the true user need and how the user need translates to the technical change. This is ensure that the change will meet the user need, and to find an alternative to meet the need, if the change isn't feasible or there is a better alternative.
- Example:
  - Wireless only Model AB+ for rechargeable
    - Real goal is to keep size comparable/smaller than current Model AB

System Interactions with Other Features

- This section serves two purposes:
  - Determining system-level functional impacts for the change
  - Determining if the change affects other system-level features
- This is a step-by-step walk through of every system feature requirement to check the following:
  - Does the change affect the feature requirement?
  - Are there any new requirements to be added due to interactions with another feature?
  - Are there any interactions to be tested even if the change doesn't drive new feature interaction requirements?

Architecture and Overall System Impact

- This is a pictoral view of where the changes are being made in the System
- Using a architectural diagram of the system to be modified, highlight the components and interfaces within the system that will need to be modified in order to support this change.
- 1-2 sentence description of the architectural changes is sufficient.

Impact to Specific Subsystems

- Identify and detail the modifications that need to made to existing subsystems to incorporate the change. This should include a preliminary assessment of all interfaces. Changes to subsystem components highlighted in the System-Level Architectural diagram should all be detailed in this section by the area expert doing the work. (e.g., if there are FW changes, that information should be contained under Firmware).

The subsystems include, but not limited to:

- Mechanical
- Electrical
- Firmware
- Application Software
- Mobile Applications
- Manufacturing Software

Testing

- New/Modified Tests – Identify impacts to system-level tests, indicating what new tests will be created and which ones can be reused/modified..
- New/Modified Test Structures/Jigs – Identify any new testing infrastructure development or changes that need to be made in order to test the change.
- Usability/Validation/System Characterization Studies – Identify any new testing that may be needed outside normal development in order to provide additional confidence before final V&V
- Manufacturing Testing– Identify impacts to Test Engineering / Manufacturing test order to incorporate this change. This will include additional test points and test procedures necessary.

System Attribute Impact

- Changes to attributes that span across system- Performance, Safety, Security, etc.

- Outline how the change may affect key system performance measures. These should include, but not limited to the effects on:
  - Power
  - Memory Utilization
  - Link budget
  - Processing speed

Applicability Impact/Future Use

- Planned use - Outline the expected applicability to a given product configuration based on the current project or scope change.
  - Can the change as proposed be used on the same product type going forward?
  - Can the change as proposed be used across product types?

- Assess future use potential. If the change can be applied to other products outside of the planned use, indicate where the change may need to be made. Include forward compatibility assessment with new developments.

Clinical/Regulatory

- Clinical
  - Are there any clinical use scenarios that are at risk?
  - Is there a need for a validation study?

- Regulatory
  - Assess if there are regulatory impact for this change related to:
    - Safety Requirements
    - EMC requirements
    - Different radios/operational frequencies
  - Check to see if external regulatory requirements have changed since last release of the product being modified. This will impact the new change.

Foreign Countries

- Identify any differences in feature behavior that need to be accommodated due to operation in a foreign country. Also include if any additional countries are added with this change or any new foreign regulations that might apply.

- Example:
  - Voice Indicators
    - Since voice indicators are recordings, recordings need to be made for each language supported

Battery Life Impact

- Does the change impact battery life?
- Example of things that impact battery life:
  - Additional drain from new HW/sensors
  - Increase in clock speed
  - Size/type of battery
  - Size/type of radio
  - Addition of accessories
- If the change impacts a sub-system area, check with the area expert if it affects their current measurement of current drain

Parameter Management

- Will *any* parameter change due to this change?
  - This is intended to trigger a review of parameter change related dependencies for this change.

Backward Compatibility Analysis

- Determine the technical scope and impact of this change to the existing legacy product configuration and/or features from a backward compatibility perspective.
  - Can devices in the field be updated with this change and still function?
  - Does the interface between FW and SW change such that older versions of FW/SW can no longer be used?

- This goes hand-in-hand with Applicability Impact

Technical Risk

- Outline the known technical risks as understood from the completion of the Systems Impact Analysis. These risks should be ordered from highest to lowest with an approximate indication of risk level per the risk scale used in the organization. These risks will be used to collectively determine the overall risk of the change and to populate the program/project risk register once the change is accepted by the project or program.

- This section should only be filled out after the Systems Impacts are completed.

Technical Unknowns

- Summarize significant technical unknowns that need to be resolved during the project and that bear on any of the impacts stated in the Systems Impact Analysis.
- SIAs are performed at the front end, so there will be technical unknowns based on discussions with area experts
- List them here – The team will determine how to resolve these unknowns post change approval. Typically these are the first things worked on at the start of the development.

Final Technical Assessment

All SIA items identified and analyzed are assessed for applicability and summarized / prioritized for the purposes of SIA.

Provide Recommendations as appropriate

- Yes or No
- Recommend an option, if there were multiple options.

Key Factors for Success

- Active elicitation of impact and ripples with area experts.
- Active assessment of elicited SIA items for applicability and making course corrections based on engineering judgment
  - Dig deeper and drive further analysis where needed.
  - Stop/contain analysis at a certain level or point in time.
  - Aggregate and summarize impacts at appropriate level of granularity/abstraction.
  - Exclude from SIA if needed.
- Systematic dispositioning / transfer of SIA items to the appropriate product development entities driving downstream work

Conclusion

Investment in SIA on projects provides:

- Holistic understanding of implications of the change
- Clear picture of all system elements affected
- Accurate estimation of the work required for the change
- Make informed decisions for the project early & upfront
- Roadmap for change management & execution
- Sound rationale and basis to support regulatory submission
- Minimize “surprises” to schedule and quality

Skipping SIA doesn’t change size and complexity of the change itself.
It just turns them into surprises!

Q&A

INCOSE
Healthcare Working Group
4th Annual Systems Engineering in Healthcare Conference

Thank you for attending!

Share your experiences at #HWGSEC