Project Performance International

Systems Engineering

Newsletter (SyEN)

SyEN #010 - July 20, 2009

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Dear Colleague,

SyEN, an independent free newsletter containing informative reading for the technical project professional, with scores of news and other items summarizing developments in the field, including related industry, month by month. This newsletter and a newsletter archive are also available at www.ppi-int.com.

Systems engineering can be thought of as the problem-independent, and solution/technology-independent, principles and methods related to the successful engineering of systems, to meet requirements and maximize value delivered to stakeholders in accordance with stakeholder values.

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We hope that you find this newsletter to be informative and useful. Please tell us what you think. Email to: contact@ppi-int.com.

We have recently changed the domain for SyEN to spread the workload across our servers. To ensure that you receive SyEN, please add our new "from" email address to your address book.

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A Quotation to Open On

"There is very little that we must do, or should do, in engineering. There are many things that we may choose to do, or choose not to do, for exactly the same reason: the rational expectation of producing a better result" - Robert Halligan

Feature Article

Medical Device Development Process

David J. Jones and Melissa T. Masters
Medical Device Solutions

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Copyright © 2008 by David J. Jones and Melissa T. Masters.

Abstract

Medical devices of increasing complexity are central to mankind's continuously expanding ability to save lives and improve the quality of life. Within our business, we often reflect on how fortunate we are to have the opportunity to work on a variety of these remarkable devices. We believe that such rewarding experiences are made possible through the application of a rigorous system engineering process, ensuring that the resulting devices are safe, effective, and successful.

This article describes a deployed System Engineering process tailored for Medical Device Development within Battelle Medical Device Solutions (MDS). This process (based on ISO 15288:2002, the INCOSE System Engineering Handbook and a Legacy Process), integrates compliance to international regulations, embeds a Safety Risk Management process as defined in ISO 14971:2007, and assures adherence to ISO 13485:2003 Quality Management Systems. Based on the classification and complexity of the device, the process is scalable, may be tailored, and is iterative.

Introduction

Medical devices range from very low risk devices (tongue depressor) to moderate risk devices (drug delivery infusion pump) to high risk devices (implanted pacemaker). In a similar fashion, the complexity in terms of functionality of medical devices range from low complexity (tongue depressor) to moderate complexity (hand-held blood glucose meter) to high complexity (an in-vitro diagnostic clinical laboratory instrument). The development of medical devices requires a wide diversity of stakeholders and disciplines as indicated in Table 1, Medical Device Development Stakeholders.

Table 1 - Medical Device Development Stakeholders

The Patient	The Patient's Caregivers (Family)	Materials Engineering
Investors	Clinicians (Nurses)	Packaging Engineering
Physicians (M.D., D.O.)	Medical Technicians	Labeling Engineering
Marketing	Sales	Software Engineering
Customer Service	Senior Management	Biomedical Engineering
Distribution Management	Device Servicing Technicians	Compliance Engineering
Regulatory Affairs	Hospital Administration	Sustaining Engineering
Project Management	Hospital Purchasing Agents	Verification Engineering
Systems Engineering	Mechanical Engineering	Manufacturing Engineering
Electrical Engineering	Human Factors Engineering	Life Scientists (Biologists)
Facilities Engineering	Industrial Design	Reimbursement Code Committee

The consequences of not being inclusive of all of the stakeholders vary from developing a medical device that no one wants to purchase, to placing a device in the market that can harm a patient. The development and manufacture of medical devices under a controlled environment is essential to assure that the device will be safe and effective in accordance with its intended use.

This article presents the results of the development and deployment of a medical device development process which meets this diverse set of conditions.

Background

A systems engineering process was used to develop the Medical Device Development Process (MDDP). The process started with elicitation of the process stakeholder needs and wants, translating the needs and wants into verifiable requirements, developing the process, verifying its implementation (did we implement what we designed) and validating (did we implement the right process). The MDDP has been in full deployment since July 2008.

The most significant stakeholder need was to have an integrated process, i.e. one process that is inclusive of the Quality Management System requirements, business policies/practices and the product development process. Previously project teams would need to understand three separate processes that were loosely coupled. The MDDP merged all three into a single process that is tightly coupled.

Figure 1, Consideration Elements for the MDDP, graphically indicates the elements that influenced the development of the MDDP.

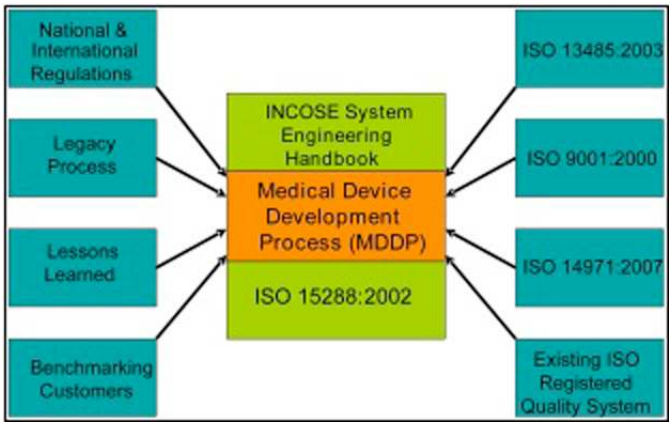

Figure 1 - Consideration Elements for the MDDP

The Medical Device Development Process

The process needed to:

- Be a repeatable process that can be applied consistently across varying scopes of projects and devices
- Be inclusive of the entire life-cycle of a medical device
- Provide clear and concise direction; only tailoring allowed will be based on the scope of the project
- Allow for Project Manager/Customer flexibility versus a rigid process
- Be a vehicle for conveyance and reinforcement of lessons learned
- Identify well-defined milestones throughout the process
- Be a functional tool for Marketing such that they can convey the process to customers
- Provide a tiered and structured approach such that different views are readily accessible, e.g. Marketing, Senior Management, Customers, Project Teams
- Provide documented direction for project teams in the form of templates, checklists, training materials, etc.
- Be harmonized with the MDS Quality System
- Be compliant with applicable regulations and standards
- Incorporate a common glossary of terms, abbreviations and acronyms
- Support an iterative process for design and development
- Recognize all stakeholders and integrate at appropriate points in the process
- Identify activities, tasks, and deliverables for each phase and the stages within a phase, clearly articulating gates with entry and exit criteria
- Clearly delineate where in the process Design Reviews need to occur
- Deploy a unified change control process with clearly articulated roles and responsibilities
- Recognize the need for defect tracking and integrate into the process
- Define a tool validation (medical device regulatory requirement) process that can be uniformly applied across projects

The design output of the MDDP resulted in an integrated process that merged the Quality Management System with the product development process. Figure 2, MDDP Design Output, illustrates the integrated process.

The MDDP has six defined phases. These phases and their transitions are shown in Figure 3, MDDP Life Cycle Phases. At the end of each Phase is a review. It is possible that all activities will not be complete at the time of this Review. The MDDP enables the project to move into the next phase based on a conditional acceptance recognizing that not all elements may be completed. Both the customer and the MDS management team need to accept the risks and align to move forward. This process will ensure that all major stakeholders are cognizant of where the project stands and are in alignment that the project should move forward or should stop until certain elements have come to closure.

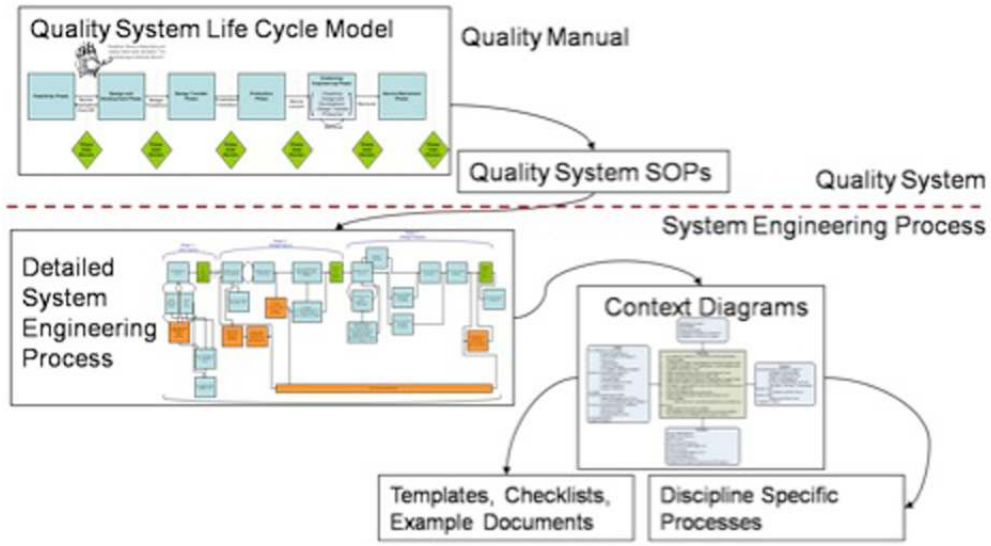

Figure 2 - MDDP Design Output

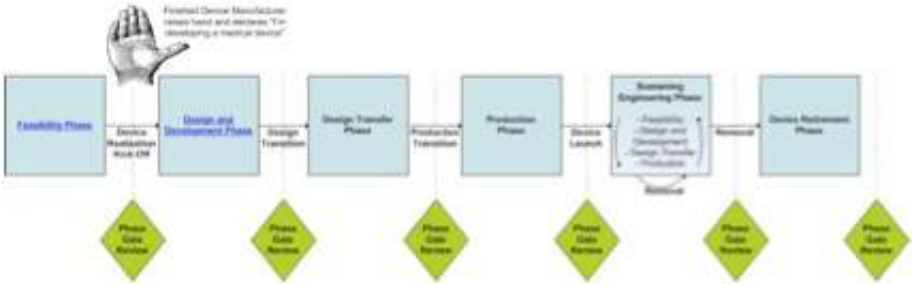

Figure 3 - MDDP Level Cycle Phases

Feasibility Phase: where the suitability of technology for a clinical need is identified and evaluated, device concepts are generated, and technical risks begin to be identified and reduced.

Design and Development Phase: where the device requirements are established and translated into a verified and validated device design.

Design Transfer Phase: where the device design is translated into production specifications.

Production Phase: where the decision has been made to proceed forward to manufacture the device for commercialization and sale, including steps to plan, promote, market, sell and also for the servicing and support of the device.

Sustaining Engineering Phase: where the marketed device is supported in its operational environment.

Device Retirement Phase: where the device is removed, dismantled, destroyed or recycled as per the manufacturer's device retirement plan.

Context diagrams were created for each phase as defined in the life cycle model, for each stage within a phase and each activity within a stage. Figure 4, Design and Development Context Diagram, illustrates a phase context diagram.

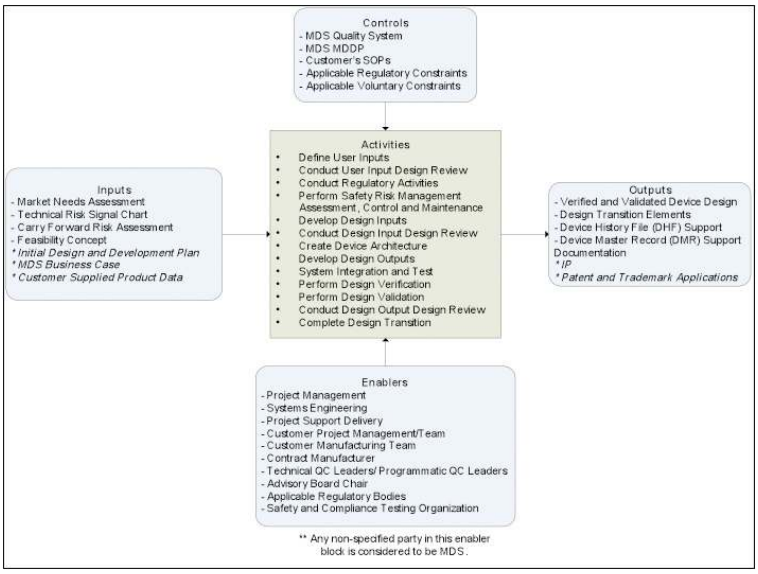

Figure 4 - Design and Development Context Diagram

Summary

The MDDP has been in full deployment since July 2008. Efficiencies are being seen in that the staff and product development teams only have one process to understand and deploy. This has reduced training burden, alleviated staff frustrations, and reduced maintenance (less processes/systems). That does not mean that the work ends here. It is critical to continually review the process and update it based on the user's experiences, updated requirements coming from regulatory and the standards we adhere to, and the latest advancements and best practices in the various tasks and activities. A team must be dedicated to ensure the process is state of the art to guide medical device development in the best, most efficient manner and most importantly create medical devices that are both safe and effective. The failure to do so can be measured both in terms of human life and financial losses to individuals and companies.

As medical devices become more integrated with other systems, combined with drugs and/or biologics, are intended for use in the home rather than in a clinic or hospital, and enter new frontiers in technology such as micro and nanotechnology, the significance of the MDDP as the backbone to medical device development becomes more apparent. A medical device designed to an intelligent, thoughtful process will yield a device that has a higher likelihood of getting to the market and making a tangible, positive difference in society.

References

ANSI/AAMI/ISO, *ANSI/AAMI/ISO 14971 Medical devices - Application of risk management to medical devices,* ISO, 2007

FDA, Center for Devices and Radiological Health, *Design Control Guidance for Medical Device Manufacturers.* March 1997

Global Harmonization Task Force, Study Group 3, *Design Control Guidance for Medical Device Manufacturers.* June, 1999

INCOSE, *Systems Engineering Handbook. v3.1 International Council on Systems Engineering.* August 2007

ISO/IEC, ISO/IEC 15288 *System engineering - System life cycle processes.* ISO, 2002

Systems Engineering News

Resilient Systems Working Group Newsletter

June. 2009, Vol. 2, Number 1

RSWG_Newsletter_4.pdf

Safety-critical software put under scrutiny

Eliminating the potential for catastrophic medical, energy and transportation disasters due to software failure is the aim of a new $21-million global research centre to be located at McMaster University. It will be one of the first such centres in the world.

More information

OMG Announces Model Interchange Working Group

OMG™ members have formed the Model Interchange Working Group (MIWG) to demonstrate and facilitate interoperability between UML®-based modeling tools. The group's initial focus is on model interchange between UML®, OMG SysML™, and Unified Profile for DoDAF and MODAF (UPDM) -capable tools. MIWG comprises end users, tool vendors and experts in the UML and XMI® standards.

More information

INCOSE and Booz Allen Hamilton Sign Systems Engineering Certification Agreement

Booz Allen Hamilton, Inc., based in McLean, Virginia, USA, and, The International Council on Systems Engineering (INCOSE) based in San Diego, California, USA, signed an agreement that will allow Booz Allen to leverage INCOSE's Certified Systems Engineering Professional (CSEP) program. Through the terms of this agreement, Booz Allen and INCOSE will collaborate in the granting of the status of CSEP to appropriately experienced Booz Allen systems engineers.

More information

Carnegie Mellon Software Engineering Institute and EDM Council Partner to Create Process for Measuring Data Management Maturity

WASHINGTON, July 8 /PRNewswire/ -- The Carnegie Mellon(R) Software Engineering Institute (SEI) and the Enterprise Data Management Council (EDM Council) today announced a strategic partnership to create a new Data Management Maturity (DMM) Model for the financial industry. The new model will be designed to define the components of data management at the specific business-process level so that financial organizations can assess themselves against documented best practices.

More information

Updated CBAP® Handbook Now Available

The Certified Business Analysis Professional™ (CBAP®) Handbook has been updated and is now available on the IIBA® website. Click here to view it now. Click here to view it now.

More information

SysML Request for Information (RFI) Issued as On-Line Survey to Support SysML Roadmap Development

June 29, 2009 - A SysML Request for Information (RFI) was issued at the June '09 OMG meeting. Response to the RFI is requested via the SysML RFI on-line survey. This information will be used as an input to develop the SysML Roadmap in support of Model-based Systems Engineering (MBSE). In addition, the response can help you assess how SysML and MBSE are being practiced within your organization. The RFI is intended to be distributed to SysML users, tool vendors, and academia to help identify how SysML is used, issues, proposed resolutions, and new features to support the roadmap. The roadmap could include a combination of incremental updates through the SysML Revision Task Force as well as a new Request For Proposal (RFP) for a significant revision to SysML. The RFI includes a survey with specific questions relative to SysML, and more general questions related to the application of SysML to model-based systems engineering (MBSE). Response are due by November 9, 2009, with the results and selected responses to be presented at the OMG SE DSIG meeting the week of December 7-11, 2009. Dr Rob Cloutier from Stevens Institute (USA) prepared the on-line survey format and will be compiling the survey results, to be made available to OMG, INCOSE, and other members of the systems engineering community.

More information

Featured Societies - Many!

List of Systems Science Organizations

Rather than feature a single professional society or other organization this month, we are publishing an overall worldwide list of

systems science and engineering organizations. The list has been compiled from PPI's own resources, acknowledging a lot of input from Wikipedia.

Systems science has been defined as the interdisciplinary field of science surrounding systems theory, cybernetics: the science of complex systems. Systems science aims to develop interdisciplinary foundations, which are applicable in a variety of areas, such as engineering, biology, medicine and social sciences. Systems science and systemics are names for all research related to systems theory. Systems science can be viewed as an evolving branch of science that studies holistic systems and tries to develop logical, mathematical, engineering and philosophical paradigms and frameworks in which physical, technological, biological, social, cognitive and metaphysical systems can be studied and developed.

The list below is organized alphabetically. For organizations that claim to be international, no country is associated with the entry.

- American Society for Cybernetics - USA
- ASEE Systems Engineering Constituent Committee - USA
- Association Francaise d'Ingénierie Système (AFIS) (French Association for Systems Engineering) - France
- Associazione Italiana per la Ricerca Ricerca sui Sistemi (AIRS) (Italian Systems Research Society) - Italy
- Australia and New Zealand Systems Group (ANZSYS) - Australia and New Zealand
- Bulgarian Society for Systems Research (BSSR) - Bulgaria
- Croatian Interdisciplinary Society - Croatia
- Cybernetics Society London - United Kingdom
- Instituto Andino de Sistemas (IAS) - Peru
- International Systems Institute
- Asociacion Mexicana de Systemas y Cibernetica - Mexico
- COSNet - Australia
- Grupo de Estudio de Sistemas Integrados (GESI) (Study Group of Integrated Systems) - Argentina
- Ελληνικη Εταρεια Συστημικων Μελετων (HSSS) (Hellenic Society for Systemic Studies) - Greece
- Gesellschaft für Wirtschaft und Sozial-Kybernetik e. V. (GWS) - Germany
- IEEE Systems, Man & Cybernetics Society (IEEE SMCS)
- IEEE Systems Council
- International Council on Systems Engineering (INCOSE)
- International Federation for Systems Research (IFSR)
- International Institute of Business Analysis (IIBA)
- International Society of Knowledge and Systems Science (ISKSS)
- International Society for the Systems Sciences (ISSS)
- Japan Association for Social and Economic Systems Studies (JASESS) - Japan
- Korean Council on Systems Engineering (KCOSE) - South Korea
- Korean Society for Systems Science Research - South Korea
- Learned Society of Praxiology - Poland
- Management Science Society of Ireland (MSSI) - Ireland
- NDIA Systems Engineering Division - USA
- Österreichische Studiengesellschaft für Kybernetik (OSGK) (Austrian Society for Cybernetic Studies) - Austria
- Polish Systems Society - Poland
- SAE Systems Engineering Cross-Industry Committee
- Slovenian Society for Systems Research (SDSR) - Slovenia
- Sociedad Espanola de Systemas Generales - Spain
- System Dynamics Society
- Systems Engineering Society of Australia (SESA) - Australia
- Systems Engineering Society of China - China
- Systemsgroep Nederland - The Netherlands
- United Kingdom Systems Society - United Kingdom
- World Organisation of Systems and Cybernetics (WOSC)

INCOSE Technical Operations

Biomedical Working Group (BWG)

http://www.incose.org/practice/techactivities/wg/biomed/

Charter

The BWG Charter is to promote practical application of systems engineering best practices and standards to the Biomedical Industry.

Leadership

Chair: Mike Celentano

Contact Mike.Celentano@incose.org for additional information or to join this group.

Planned Work

- Map Biomed to SE Terms – Wiki in progress
- Map Biomed to SE Process - ongoing
- ID Current Best Practices – 3 workshops in progress from members
- Biomed annex for INCOSE Handbook with CSEP – long term plan
- Pursuing Synergy with biomed orgs & INCOSE WGs
- Org Conf Panel/Tracks
    - Biomed track at IS10 in Chicago. The WG is in the process of collecting volunteers for Biomed papers.

Joint Activities and Products

- IS08 Paper Mapping Biomed to SE
- April 2009 Engineering Society of Detroit Collaboration Conference
- Collaboration started with REGAL, RWG, RMWG, MWG, MDSDWG, HSIWG

Presentations

2008 International Workshop Biomedical WG Summary Presentation - Size: 200k

Systems Engineering Software Tools News

Advance Notice of Cradle-6.0 Release

3SL announced in their June 2009 Cradle© Newsletter that they confidently expect to release the next major Cradle version, Cradle-6.0, imminently.

More information

MagicDraw UML Wins Design and Modeling Category Award at Great Indian Developer Summit

(OPENPRESS) June 13, 2009

The Summit's design and modeling category honored leaders in requirements gathering, modeling, prototyping, GUI design and analysis tools. The award selection criteria applied by an international panel places emphasis on functionality, usability, innovation excellence and user feedback.

Paul Duncanson, Chairman and President of Asian and European Operations at No Magic received the prestigious award on behalf of the No Magic, MagicDraw UML team.

More information

SysML plugin 16.5 SP 2 is Released

Posted June 18th, 2009 by No Magic in Software Colorado

No Magic Inc. announced the release of SysML plugin 16.5 SP2. This Service Pack 2 has fixed numbering requirement IDs, extract structure, SysML dependency matrix templates and other minor issues.

More information

Practical UML and URDAD Based Modeling Using MagicDraw in Johannesburg

UML and URDAD (Use Case Responsibility-Driven Analysis & Design) based modeling is offered in the Johannesburg area (South Africa).

More information

Best Practices for Model-based Systems Engineering

Based on a small set of key principles and practices from the IBM® Rational® Harmony™ library of best practices, the Harmony for Systems Engineering process provides step-by-step guidance on who does what, and when they have to do it. Harmony for Systems Engineering is a model-based development process built upon the UML and SysML languages. These standard-compliant languages allow Harmony for Systems Engineering to seamlessly integrate systems engineering and software development. Harmony for Systems Engineering incorporates overall project flow with efficient design iterations to improve stakeholder requirements definition, requirements analysis, design synthesis, interface definition and early validation via executable models. (Source:IBM)

More information

Systems Engineering Books, Reports, Articles and Papers

Unleashing the Next Wave of Engineering Innovation

By Cameron Burns, June 11, 2009, GreenBiz.com

..."Engineering schools don't specifically teach bad engineering design," notes RMI's Alok Pradhan, "It's just that current engineering practice is very siloed and there's a lack of integration and whole-system consideration. Designs are typically optimized for the wrong parameters. That is, they will optimize the component individually, and the pieces -- when they fit together - don't work that great as a system."...

...Pradhan is the project manager for 10xE, which is short for Factor Ten Engineering. Several years ago, RMI kicked off this modest project to address these problems in engineering. This RMI initiative is fairly straightforward: The goal is to create a series of teaching tools that will help engineers design the things they design using radically less energy and resources than they otherwise would have, without compromising performance. These teaching materials - revolving around a casebook of extremely efficient projects and systems -- will be used to teach efficiency concepts and design to both engineering students and practitioners...

More information

Pairing CMMI and Six Sigma for Optimal Results

June 12, 2009 - Contact Centre Solutions Community

Leapfrog your competition by following these claimed fool-proof strategies for accelerating process improvement. Discover how Six Sigma and CMMI can work together to bring about effective change within your organization.

More information

Systems Thinking Blog Series

This series of blogs focus on basic systems thinking as it is applies to our energy structure. It will also integrate some of the learning that lean practices provide, as well as the scientific principles of The Natural Step. The learning will only touch the surface with the hope that you will take the learning and/or ideas further and, as importantly, applying the learning in the job you are in now. The intent is to focus on leverage points of complex systems, so we can move our complex energy system more toward results we desire. Unfortunately, the behavior of complex systems involves collapses and oscillations, not linear behavior lines. A challenge for us is that to change complex system behavior is often counter-intuitive. Also, complex systems will surprise us because we can't understand and anticipate all interactions within a series of complex subsystems comprising an overall system.

Part 1

Part 2

Part 3

Part 4

How Do We Become a Systems Thinking Organization?

Monday, June 22, 2009 by Tripp Babbitt

"A natural question for the curious is "how to do something." What are the steps to becoming a systems thinking organization? The answer I will leave you in this blog will be somewhat of a paradox consistent with the discipline itself. First of all, you can't copy another organization, each organization is unique and part of systems thinking is understanding that copying can lead to more problems. And it was Dr. W. Edwards Deming that said that it is difficult for an organization to see itself. So combining theory and knowledge the Vanguard Method takes organizations through a learning model that requires an unlearning and relearning method to change thinking. We believe that this is best done with the work so one can see the waste and inefficiency in your organization."

More information

Handbook of Systems Engineering and Management

by Andrew P. Sage (Author), William B. Rouse (Author)
Publisher: Wiley-Interscience; 2 edition (April 20, 2009),
ISBN-10: 0470083530, ISBN-13: 978-0470083536

The handbook is written and edited for systems engineers in industry and government, and to serve as a university reference handbook in systems engineering and management. It is primarily focused on systems engineering and systems management for fielding systems of all types, especially systems that are information technology and software intensive and which involve human and organizational elements. By focusing on systems engineering processes and systems management, the editors continue to produce a long lasting handbook that will make a difference in the design of systems of all types that are large in scale and/or scope.

More information

Software & Systems Requirements Engineering: In Practice

by Brian Berenbach, Daniel Paulish, Juergen Kazmeier, and Arnold Rudorfer
Publisher: McGraw-Hill Osborne Media; 1 edition (March 26, 2009), ISBN-10: 0071605479, ISBN-13: 978-0071605472

Proven Software & Systems Requirements Engineering Techniques

"Requirements engineering is a discipline used primarily for large and complex applications. It is more formal than normal methods of gathering requirements, and this formality is needed for many large applications. The authors are experienced requirements engineers, and this book is a good compendium of sound advice based on practical experience." - Capers Jones, Chief Scientist Emeritus, Software Productivity Research

Deliver feature-rich products faster, cheaper, and more reliably using state-of-the-art SSRE methods and modeling procedures. Written by global experts, Software & Systems Requirements Engineering: In Practice explains how to effectively manage project objectives and user needs across the entire development lifecycle. Gather functional and quality attribute requirements, work with models, perform system tests, and verify compliance. You will also learn how to mitigate risks, avoid requirements creep, and sidestep the pitfalls associated with large, complex projects.

- Define and prioritize customer expectations using taxonomies
- Elicit and analyze functional and quality attribute requirements
- Develop artifact models, meta-models, and prototypes
- Manage platform and product line development requirements
- Derive and generate test cases from UML activity diagrams
- Deploy validation, verification, and rapid development procedures
- Handle RE for globally distributed software and system development projects
- Perform hazard analysis, risk assessment, and threat modeling

More information

Early Verification and Validation Using Model-based Design

By Brett Murphy and Amory Wakefield, The MathWorks -- EDN, 7/9/2009

...The rapid growth in processor speed and memory that enabled the development of modeling, simulation, and code-generation tools on the desktop also enabled embedded-software developers to increase the functions and complexity of embedded

controllers. This step in turn drove the need to move beyond traditional code-development techniques using text editors and debuggers to center design on models. This model-centric development approach is known as model-based design…. ... The primary way model-based design achieves verification and validation is through testing in simulation. Although many organizations do some form of modeling, too many apply simulation in an ad-hoc manner that does not maximize the potential verification benefits. Simulation alone cannot find all errors; however, it is a huge step forward, and you can do it almost as soon as you design a model. Iterating in a modeling environment is fast and easy...

More information

MBSE and SysML Models

COFES Blog - Jack Ring

...In software there were few physical rules to be automated. For those writing device drivers the design of the hardware gave good guidance. Likewise for those writing control programs for microprocessors. But when it came to 'applications' the rules were much less clear...

...We became convinced that success in computer-aids for software engineering would not lie in physics-based models but in models of how designers think (or not) and how to facilitate higher order thinking (Janusian, Hegelian, etc.)...

...Models are essential. I think we all have demonstrated that specifications or other written descriptions ABOUT things, the interaction among things and the interactions among the interactions simply do not communicate...

...For second order or higher implicit systems a key factor is that any modeling language and tool must allow a model of the system to be one of the 'things' in the system and allow the model to affect the system's gradients, pattern of relationships and even content of 'things.' I have yet to see how SysML allows that...

More information

An overview of UPDM - A Unified Profile for DoDAF/MODAF

By Matthew Hause - ARTISAN SOFTWARE TOOLS

Considering the large variety of military architectural frameworks in existence such as DoDAF and MODAF, among others, a way to unite their differing requirements has recently been born: the Unified Profile for DoDAF and MODAF (UPDM), which works toward a standardized UML/SysML profile for these and other military frameworks.

More information

Conferences and Meetings

INCOSE 19th Annual International Symposium (IS) 2009

July 20 - 23, 2009. Singapore
More information

3rd Annual International Workshop on Requirements Engineering for Services (REFS'09)

In conjunction with COMPSAC 2009, July 20 - 24, 2009. Seattle, Washington
More information

2nd IEEE International Workshop on Industrial Experience in Embedded Systems Design (IEESD 2009)

In conjunction with COMPSAC 2009, July 20 - 24, 2009. Seattle, Washington
More information

2009 International Conference of the System Dynamics Society

July 26 - 30, 2009. Albuquerque, New Mexico

More information

PICMET '09 Conference: "Technology Management in the Age of Fundamental Change"

August 2 - 6, 2009. Hilton Portland and Executive Tower, Portland, Oregon, USA
More information

CGBDP - VII Brazilian Congress on Product Development Management

August 3 - 5, 2009. Embraer Eugenio de Melo, Brazil
More information

Innovation 2009 - As Real as it Gets

August 4 - 5, 2009. Histon Hotel, Sydney, Australia.
More information

Improving Systems and Software Engineering Conference (ISSEC 2009)

Co-located with the 6th Annual Project Management Australia Conference (PMOZ 2009). August 10 - 12, 2009. Canberra, Australia
More information

Workshop on Logical Aspects of Fault Tolerance (LAFT)

(affiliated with LICS 2009). August 15, 2009. University of California, Los Angeles, USA
More information

17th IEEE International Requirements Engineering Conference (RE'09)

31 August - 4 September 2009, Atlanta, Georgia, USA
More information

Workshop on Collaboration and Intercultural Issues on Requirements: Communication, Understanding and Softskills (CIRCUS)

In Conjunction with 17th IEEE International Requirements Engineering Conference (RE'09).
31 August, 2009. Atlanta, Georgia, USA
More information

Doctoral Symposium at RE'09

1 September, 2009. Atlanta, Georgia, USA.
More information

4th International Workshop on Requirements Engineering Vizualisation (REV'09)

31 August, 2009. Atlanta, Georgia, USA.
More information

4th International Workshop on Requirements Engineering Education and Training

31 August, 2009. Atlanta, Georgia, USA.
More information

2nd International Workshop on Managing Requirements Knowledge (MaRK '09)

In conjunction with the 17th IEEE Requirements Engineering Conference
1 September, 2009. Atlanta, Georgia, USA
More information

2nd International Workshop on Requirements Engineering and Law

In conjunction with the 17th IEEE Requirements Engineering Conference
1 September, 2009. Atlanta, Georgia, USA
More information

1st Workshop on Service-Oriented Business Networks and Ecosystems (SOBNE '09)

1 September, 2009. Auckland, New Zealand.
More information

Business Analyst World NEW

1 - 2 September, 2009, Wellington, New Zealand. More information
7 - 8 September, 2009, Auckland, New Zealand.
16 - 17 September, 2009, Perth, Australia.
21 - 22 September, 2009, Canberra, Australia.
5 - 6 October, 2009, Denver, USA.
5 - 6 October, 2009, Edmonton, Canada.
5 - 7 October, 2009, Brisbane, Australia.
19 - 22 October, 2009, Boston, USA.
26 - 29 October, 2009, Vancouver, Canada.
16 - 19 November, 2009, Chicago, USA.
30 November - 1 December, 2009, Ottawa, Canada.

European Systems & Software Process Improvement and Innovation (EuroSPI2)

September 2 - 4, 2009. University of Alcala, Spain
More information

3rd International Workshop on Enterprise Modeling and Information Systems Architectures

10 - 11 September, 2009. Ulm University, Germany
More information

AIAA Space 2009 - Joint Space Systems Engineering and Economics Track

Within the conference is a joint Space Systems Engineering and Economics Track that has room for slots for four space systems engineering papers. September 14 - 17, 2009. Pasadena, CA, USA

Download Call for Papers

Additional Conference Information

Third IEEE International Conference on Self-Adaptive and Self-organising Systems (SASO'09)

(IEEE approval pending)

September 14 - 18, 2009. San Francisco, USA

More information

SEPG Asia-Pacific 2009

September 16 - 18, 2009. Osaka, Japan.

More information

ICAPS 2009 Workshop on Verification and Validation of Planning and Scheduling Systems (VV&PS 2009)

September 19 - 20, 2009. Thessaloniki, Greece.

More information

14th System Design Languages Forum

September 22 - 24, 2009. Ruhr-University of Bochum, Germany
More information

ICISE 2009 - International Conference on Industrial and Systems Engineering

September 23, 2009, Toronto, Canada.
More information

Ninth International Workshop on Automated Verification of Critical Systems (AVoCS 2009)

Swansea University Computer Science, September 23 - 25, 2009.
More information

28th International Symposium on Reliable Distributed Systems 

September 27 - 30, 2009, Niagra Falls, USA.
More information

Workshop "Games, Business Processes and Models of Interactions"

September 28, 2009, University of Lubeck, Germany.
More information

Systems Thinking in Schools: Level 1 Workshop

September 29 - October 2, 2009. Cavendish Road State High School, Holland Park, QLD, Australia.
More information

12th Australian Workshop on Requirements Engineering (AWRE'09)

October 1 -2, 2009. University of Technology, Sydney, Australia.
More information

Workshop "Integration Engineering" held at the annual meeting 2009 of the Gesellschaft fuer Informatik e.V. (GI)

October 2, 2009, University of Lubeck, Germany.
More information

ACM/IEEE 12th International Conference on Model Driven Engineering Languages and Systems (formerly the UML series of conferences)

4 - 9 October, 2009, Denver, Colorado, USA.
More information

Educators' Symposium at MODELS 2009 NEW

4 - 9 October, 2009, Denver, Colorado, USA.
More information

2nd International Workshop on Model Based Architecting and Construction of Embedded Systems (in conjunction with MODELS 2009)

6 October, 2009. Denver, Colorado, USA.
More information

Track Systems Engineering 2009

7 - 8 October, 2009, Munich, Germany.
More information

2009 SEER by Galorath North American User Conference: Best Practices in Project Estimation, Planning & Control

8 - 9 October, 2009. Porofino Hotel, California, USA.
More information

International Conference on Man-Machine Systems (ICoMMS)

11 - 13 October, 2009, University of Malaysia Perlis.
More information

7th International Symposium on Automated Technology for Verification and Analysis NEW

13 - 16 October, 2009, Macao SAR, China.
More information

Symposium on Automotive/Avionics Systems Engineering SAASE 2009

14 - 17 October, 2009, San Diego, CA, USA.
More information

12th Annual Systems Engineering Conference

26 - 29 October, 2009, San Diego, CA, USA.
More information

Formal Methods for Industrial Critical Systems (FMICS) 2009

2 - 3 November, 2009, Eindhoven, The Netherlands.
More information

16th International Symposium on Formal Methods (FM2009)

2 - 6 November, 2009, Eindhoven, The Netherlands.
More information

FM 2009 Doctoral Symposium NEW

6 November, 2009, Eindhoven, The Netherlands.
More information

28th International Conference on Conceptual Modeling

9 - 12 November, 2009, Gramado, RS, Brazil.
More information

Workshop on Requirements, Intentions and Goals in Conceptual Modeling

9 - 12 November, 2009, Gramado, RS, Brazil.
More information

1st Annual Global Conference on Systems and Enterprises (GCSE)

2 - 4 December, 2009. Singapore.
More information

INCOSE 2010 International Workshop NEW

7 - 10 February, 2010. Phoenix Marriott Mesa, Mesa, Arizona.
More information

1st Workshop on Semantically-Enabled Systems Engineering (SENSE-2010) NEW

15 - 18 February, 2010. Andrzej Frycz Modrzewsk Cracow College, Krakow, Poland.
More information

IESS 1.0: First International Conference on Exploring Services Sciences

17 - 19 February, 2010. Geneva, Switzerland.
More information

Track on REAL-TIME SYSTEMS at ACM SAC 2010 NEW

21 - 26 March, 2010. Sierre, Switzerland.
More information

The Third Edition of the Requirements Engineering Track (RE-Track'10)

22 - 26 March, 2010. Sierre, Switzerland.
More information

Agent-Directed Simulation Symposium (ADS 2010)

12 - 15 April, 2010, Orlando, Florida, USA.
More information

COFES: Congress on the Future of Engineering Software (COFES) 2010 NEW

15 - 18 April, 2010, Scottsdale, Arizona, USA.
More information

Systems Engineering and Test & Evaluation (SETE) 2010 NEW

3 - 6 May, 2010, Stamford Grand, Adelaide.
More information

EuSEC 2010: Systems Engineering and Innovation NEW

23 - 26 May, 2010, Stockholm, Sweden.
More information

20th Annual INCOSE International Symposium NEW

11 - 15 July, 2010, Rosemont, IL, USA.
More information

Fourth Asia-Pacific Conference on Systems Engineering (APCOSE 2010)

11 - 13 September, 2010. Keelung, Taiwan.
More information

Education & Academia

Thinking in Systems: Practical Lessons for Building Sustainable Organizations & Communities

Inspired by the book Thinking in Systems - A Primer by Donella Meadows, isee systems has developed a web seminar series in collaboration with Pontifex Consulting and the Sustainability Institute.

More information

Open University (UK) Offers Research Studentships

The Open University (UK), in celebration of its 40th anniversary, is offering a number of research studentships. They will cover all fees for three years plus an annual stipend, and are tenable from 1 October 2009. Application deadline is 24th July 2009.

Some of the topics on offer are:

- Analysing inconsistency in evolving security requirements
- Requirements Engineering and Climate Change

For more information on topics, supervisors and an application pack, visit http://www.openuniversity.co.uk/studentship

Some Systems Engineering-Relevant Websites

http://www.newsystemsthinking.com/
Bryce Harrison (in partnership with Vanguard Consulting Ltd) helps organizations change from command and control to a systems approach in the design and management of work. This is accomplished by supplying expertise in:

- The Vanguard Method©: How changing to a "systems" design of work would improve an organization's performance.
- Interventionist skills: How to go about making and sustaining these changes. International clients have said that working with the Vanguard Method has been the most important change in thinking that they have ever experienced in their working life.

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http://www.lean-solutions-institute.com/
The vision of Lean Solutions Institute, Inc. (LSI) is to be recognized worldwide as the leader in helping clients to become lean, to help clients achieve lean measurable results (e.g., 7:1 ROI), and to provide clients with best-in-class Lean Solutions - (e.g., processes, metrics, checklists, templates, etc).

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http://rationalrdm.wordpress.com
A blog by Theresa Kratschmer, requirements evangelist. The IBM Rational Requirements team uses this blog as a forum to discuss various issues around their next generation requirements management solutions - and give inside access to the engineering, product and marketing teams behind the new IBM Rational Requirements Composer, as well as Rational RequisitePro and Rational DOORS.

Standards and Guides

Recommended Practice for Architectural Description of Software-Intensive Systems ANSI/IEEE Std 1471 : ISO/IEC 42010

In July 2007, ISO published ISO/IEC 42010:2007, Systems and software engineering - Recommended practice for architectural description of software-intensive systems. The text of this ISO standard is identical to IEEE 1471:2000, and was intended to serve as basis for a joint ISO and IEEE revision.

That revision has been proceeding, and is of Working Draft 4 (WD4) status. The revision includes an expansion of scope to directly align to ISO/IEC 15288 (systems) as well as ISO/IEC 12207 (software).

More information

Two New Electromagnetic Compatibility Standards now Available

BS EN 61000-4-2:2009

Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test.

BS EN 61000-4-6:2009

Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.

Some Definitions to Close On - Performance, Performance Requirement

Performance

The degree to which a system or component accomplishes its designated functions within given constraints, such as speed, accuracy, or memory usage
(ISO/IEC 24765:2008, Systems and software engineering vocabulary)

Note from Robert Halligan: despite the ISO/IEC 24765:2008 definition, memory usage is not a measure of performance, since it is not a measure of the degree to which the system accomplishes/is to accomplish a designated function.

Performance Requirement

1. the measurable criterion that identifies a quality attribute of a function or how well a functional requirement must be accomplished
   (IEEE 1220-2005, IEEE Standard for the Application and Management of the Systems Engineering Process , 3.1.26)
2. a system or software requirement specifying a performance characteristic that a system/software system or system/software component must possess (ISO/IEC 24765:2008, Systems and software engineering vocabulary)
3. a requirement that imposes conditions on a functional requirement (ISO/IEC 24765:2008, Systems and software engineering vocabulary)

Project Performance International News

PPI has closed its office in São José dos Campos, Brazil. Mr. Joshua Freeman will now be the point of contact for the training needs of PPI's clients in Brazil. PPI remains committed to Brazil and to South America, with seven courses scheduled in 2009/2010, and attendance at XSIGE & SPOLM conferences in the coming months.

Our new Brazil contact numbers are phone +55 12 3212 2017, and fax +55 12 3212 5582, both answering in Australia.

O PPI fechou seu escritório em São José dos Campos - SP, mas permanece empenhado no Brasil e América do Sul, com sete cursos programados em 2009/2010 e participação em conferências XSIGE & SPOLM nos próximos meses. O Sr. Joshua Freeman será, a partir de agora, seu contato para o esclarecimento de dúvidas necessárias sobre os cursos (ou o diretor Robert Halligan, de dúvidas de ordem profissional).

Os telefones para contato com os nossos escritórios são (12) 3212-2017 ou Fax (12) 3212-5582.

Project Performance International Events

Systems Engineering 5-Day Courses

Upcoming locations include:

- Sydney, Australia
- Adelaide, Australia
- Munich, Germany
- Singapore
- Rio de Janeiro, Brazil
- Cape Town, South Africa
- Las Vegas, USA

View 2009 Systems Engineering Course Schedule

Requirements Analysis and Specification Writing 5-Day Courses

Upcoming locations include:

- Las Vegas, USA
- Melbourne, Australia
- Cape Town, South Africa
- Amsterdam, The Netherlands
- Adelaide, Australia

View 2009 RA&SW Course Schedule

OCD/CONOPS 5-Day Courses

Upcoming locations include:

- Adelaide, Australia
- Las Vegas, USA
- Pretoria, South Africa

View 2009 OCD/CONOPS Course Schedule

Software Engineering 5-Day Courses

Upcoming locations include:

- Pretoria, South Africa
- Adelaide, Australia
- Amsterdam, The Netherlands

Cognitive Systems Engineering 5-Day Courses

Upcoming locations include:

- Adelaide, Australia
- London, UK
- Las Vegas, USA

View 2009/10 Cognitive Systems Engineering Course Schedule

PPI Upcoming Participation in Professional Conferences

- 20 - 23 July, 2009 - **INCOSE International Symposium 2009** - Singapore (Exhibiting)
- 20 - 23 July, 2009 - **MICSSA 2009** - Pretoria, South Africa (Silver Patron)
- 18 - 22 August, 2009 - **INCOSE South Africa 2009** - Pretoria, South Africa (Gold Sponsor)

Kind regards from the SyEN team:
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