

Crossroads of America

Panel Discussion

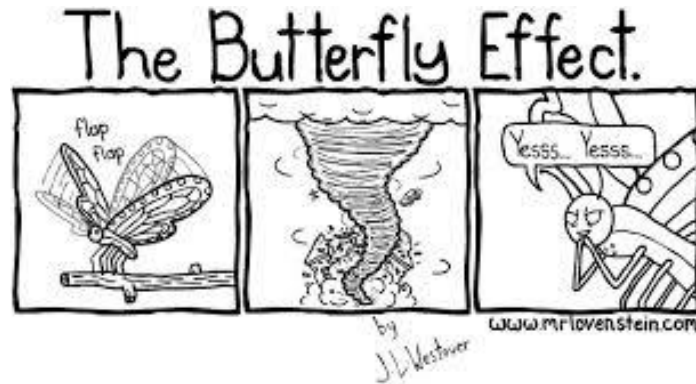
14 August, 2018

Mike Celentano

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Value of SE - how would you articulate the value of using a Systems Engineering approach? ... Joshua



Why SE?

The Whole > Sum of the Parts

The Whole System =

Sum of the Parts + All Interactions + Users

Over the Life of the System

SEs Champion understanding these interactions.

This improves project & product outcomes!

Example: I was asked by a stakeholder to "prove" the ROI of the weekly multi-discipline System FMEAs I ran.

So, each week I reported the critical failures we prevented.

This satisfied that question of value, without further concern.

Lee Oukrop holds a high school senior portrait of his late son. Joshua had an implanted heart defibrillator made by Guidant and died on a bicycling trip in March 2005 after the device short-circuited. AP 6/24/2005



Guidant knew about the potential failure, fixed it in newly made devices, and decided not to recall the devices in the field.

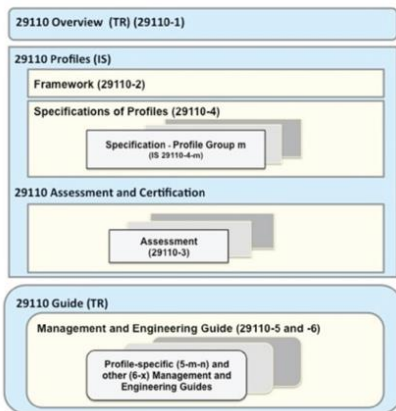
NY Times 5/24/2005

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How to do an effective but minimalist SE approach to a design with a very limited budget? ... **Assess & Tailor**

Figure 1 — ISO/IEC 29110 series



ISO/IEC 29110 (VSE WG still actively adding to this STD)

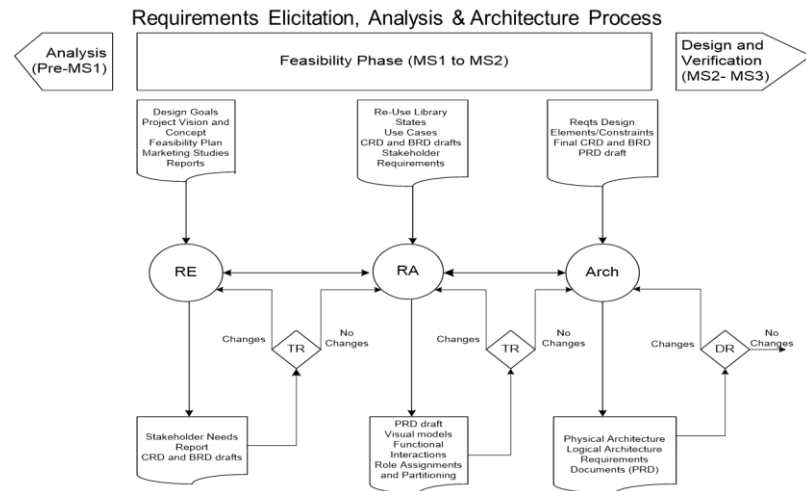
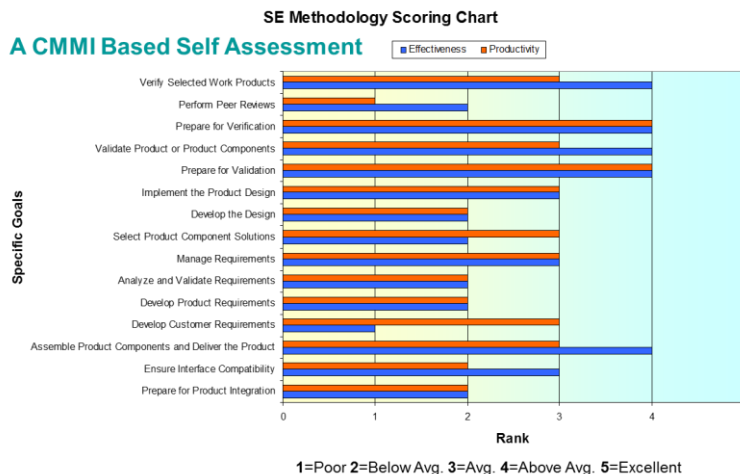
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Harmonized w/ ISO/IEC/IEEE 15288:2015

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Example: Long ago I was challenged to improve our Development Process with little to no budget.

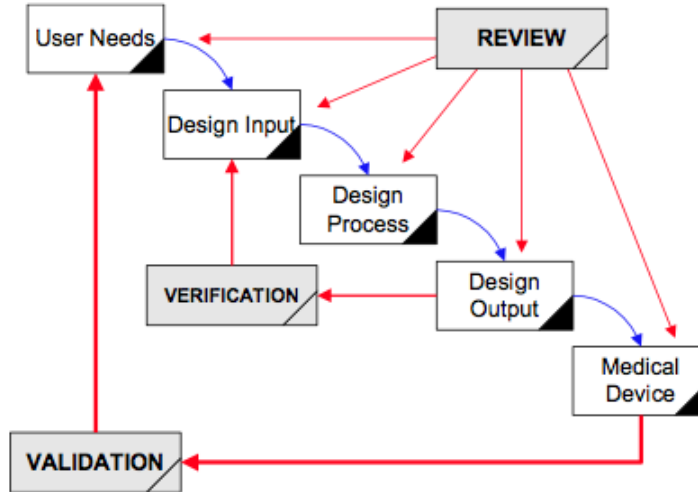


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Verification and Validation - what's the difference and does it matter? ... Context & Yes!!

Code of Federal Regulations 820.3



Verification has a requirements & performance context ...
Did we design it right?

Validation has a user and product context ...
Did we make the right thing?

Food for thought & debate ...

- What is "Requirements Validation", does it include the user or product?
- What is "System Verification", should it not include the user & product?

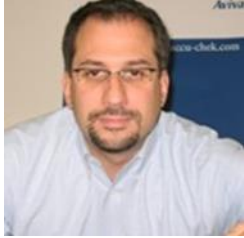


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Let the Questions & Discussions Commence 😊

Thanks!



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Mike Celentano has been influencing the Medical Diagnostics field since 1987. He has experience in systems engineering, advanced research, engineering management, product development, and technology management.

Mike has dedicated his career to developing multi-disciplined instrumentation used to diagnose & monitor disease to ultimately help improve the quality of healthcare globally. He has worked for Technicon, Miles, Bayer, Seradyn, UMM and Roche. Mike is currently the Program Leader for Global Adaptive Technologies at Roche Diagnostics Diabetes Care in Indianapolis. His charter is to evaluate and expedite new technologies and features that could benefit Roche's diabetes patients, caregivers, and payers.

Mike has a B.S. in Electrical Engineering from N.Y.I.T. He achieved SE certification at the highest level in 2017. Mike has been granted many global patents related to medical diagnostics. Through his involvement in INCOSE Mike is striving to make Systems Engineering practices more common-place in the Biomedical Industry. Mike founded the INCOSE International Healthcare Working Group. He currently serves on the Board of Directors for INCOSE at the international level.