# Building An Assurance Case And What Is Needed To Complete These Models



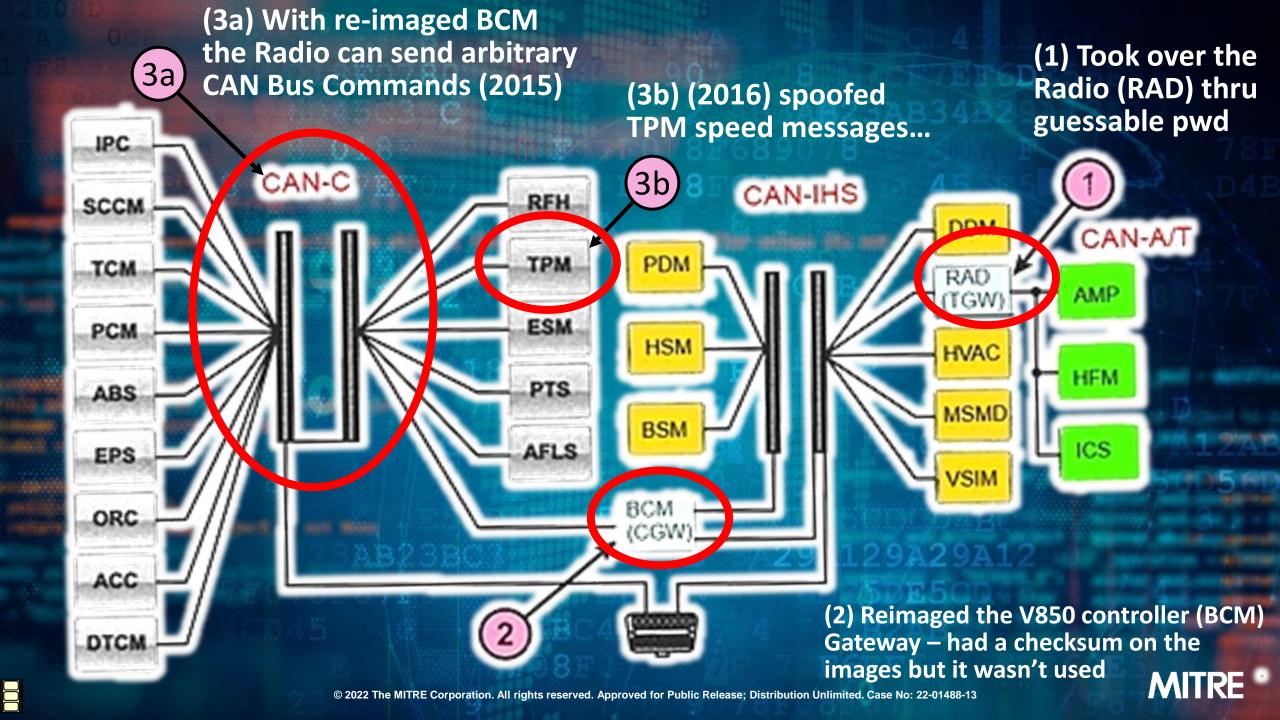
Sr. Software and Supply Chain Assurance Prin. Eng. Cross Cutting Solutions and Innovation Dept. Cyber Solutions Technical Center MITRE Labs

August 31, 2022

A Presentation to the 2022 NDIA Electronics Trust & Assurance Subcommittee Workshop at Lockheed Martin Global Vision Center, Arlington, VA







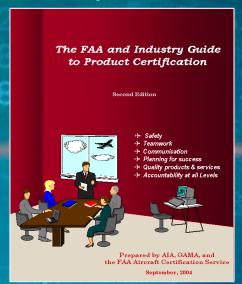
# Certified to Work in Shared Context Engineered to Do the Mission...



Critical	2005 Operational Evaluation								
Operational Issue	Parameter	Threshold	Result						
	Amphibious Pre- Assault/Raid	200 NM (KPP)	230 NM						
	Amphibious Ext Lift	10,000 lbs for 50 NM (KPP)	9,800 for 50 NM						
Assault Support	Land Assault External Lift	50 NM (KPP)	69 NM						
	Cruise Airspeed	240 KTS (KPP)	255 KTS						
	Troop Seating	24 Combat Troops (KPP)	24 Combat Troops						
Self Deployment	Self-deployment	2100 NM (KPP)	2660 NM						
Survivability	Ballistic Tolerance	12.7mm @ 90% velocity (KPP)	Satisfactory (BLRIP-LFT&E)						
Interoperability	Top Level Information Exchange Requirement (IER)	All top-level requirements (KPP)	Satisfactory						

### **FAA Flight Certified**

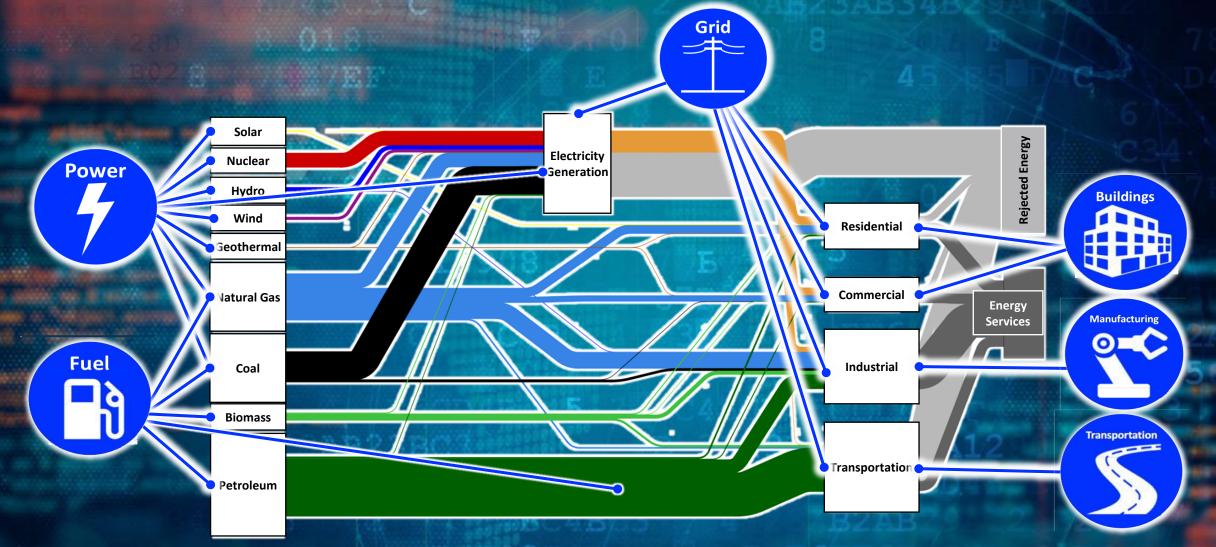
 Radios, Radar Beacons, Navigation Lights, Safety features...







# Need Standards to Drive Consistency in Discussing and Conveying Assurance due to the Sector-2-Sector linkages





# Perspectives on Assurance

### Insurer

How do I underwrite?

### Researcher

 What technology is needed to ensure trust?

### Creator

- How should I design and build?
- Will I be liable for problems?

### Operator

- How do I use this?
- · Can I trust it?
- Am I responsible if it makes a mistake?



### Commander/ Supervisor

- Can I reliably use in operations?
- What changes operationally?

## Community

- Do I want this in my backyard?
- Can I count on it?

## Regulator

• Is it safe?

### Acquirer

- How do I express requirements?
- Will it work they way it should?



### Patron

- Is it safe?
- Should I use it?
- Can I count on it?

# Definition of Assurance Case

A documented body of evidence that provides a convincing and valid argument that a specified set of critical claims regarding a system's properties are adequately justified for a given application in a given environment.

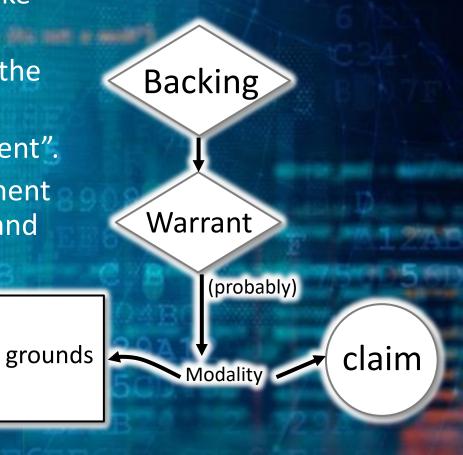


## **Assurance Claims with Support of 'Substantial' Reasoning**

- Claims are assertions put forward for general acceptance
- The justification for claim based is on some grounds, the "specific facts about a precise situation that clarify and make good for a claim"
- The basis of the reasoning from the grounds (the facts) to the claim is articulated.
- Toulmin coined the term "warrant" for "substantial argument".
- These are statements indicating the general ways of argument being applied in a particular case and implicitly relied on and whose trustworthiness is well established".
- The basis of the warrant might be questioned, so "backing" for the warrant may be introduced.
   Backing might be the validation of the scientific and engineering laws used.



Stephen Toulmin, 1958

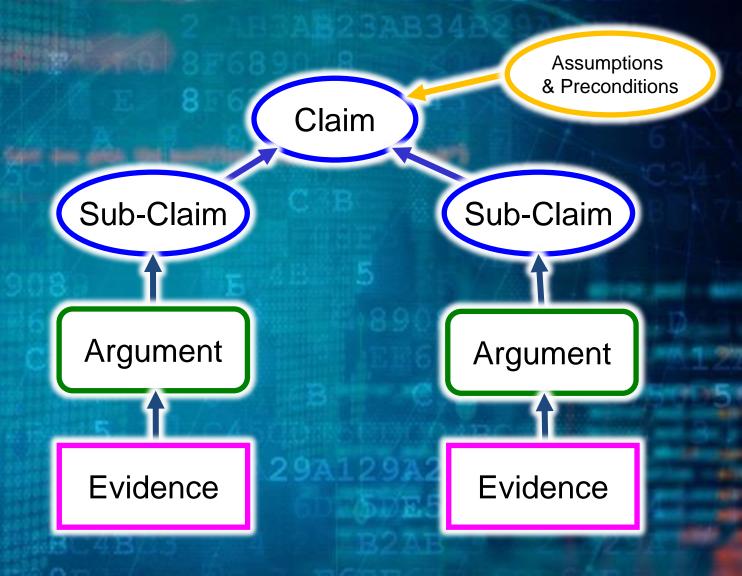


# The Basics of an Assurance Case

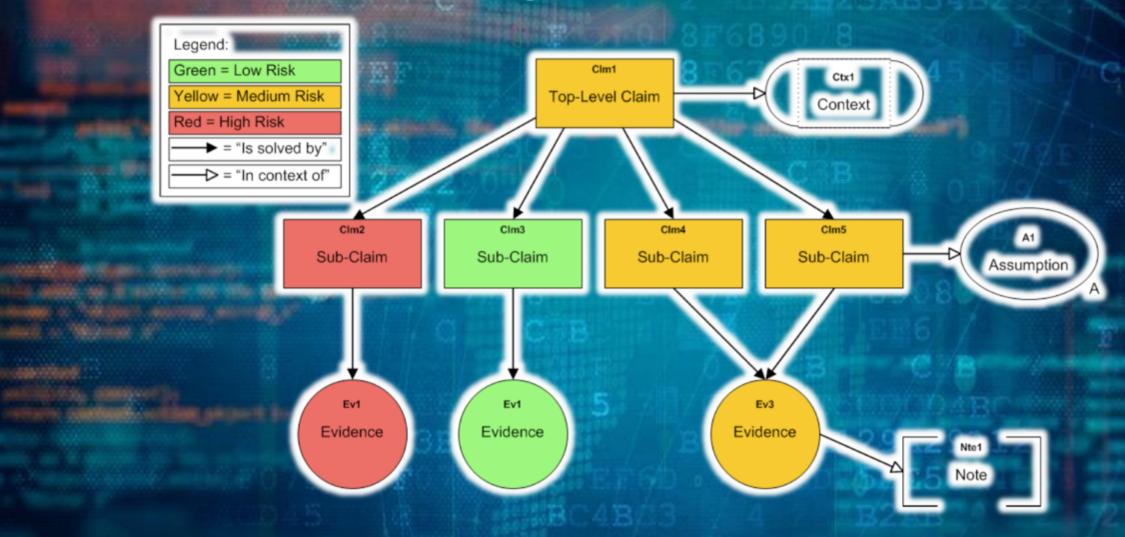
Claim = assertion to be proven

Argument = how evidence supports claim

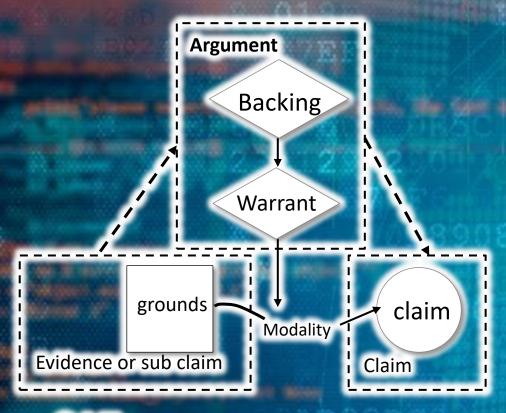
Evidence = required documentation



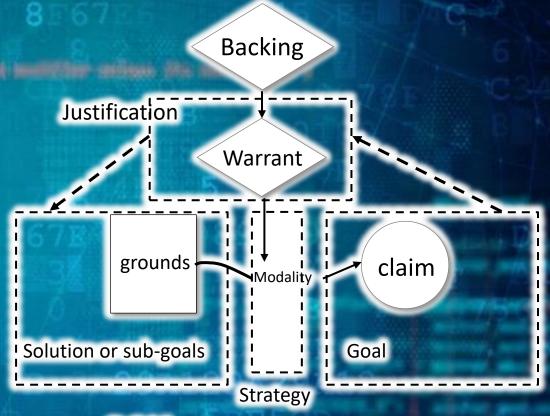
# Safety Case Tooling – Claims-Evidence-Argument in Use for <15 Years



# Assurance Claims with Support of 'Substantial' Reasoning → two implementations



CAE Claim, Argument, Evidence



GSN Goal Structuring Notation

# ISO/IEC 15026: Systems & Software Assurance Part 2: The Assurance Case (Claims-Evidence-Argument)



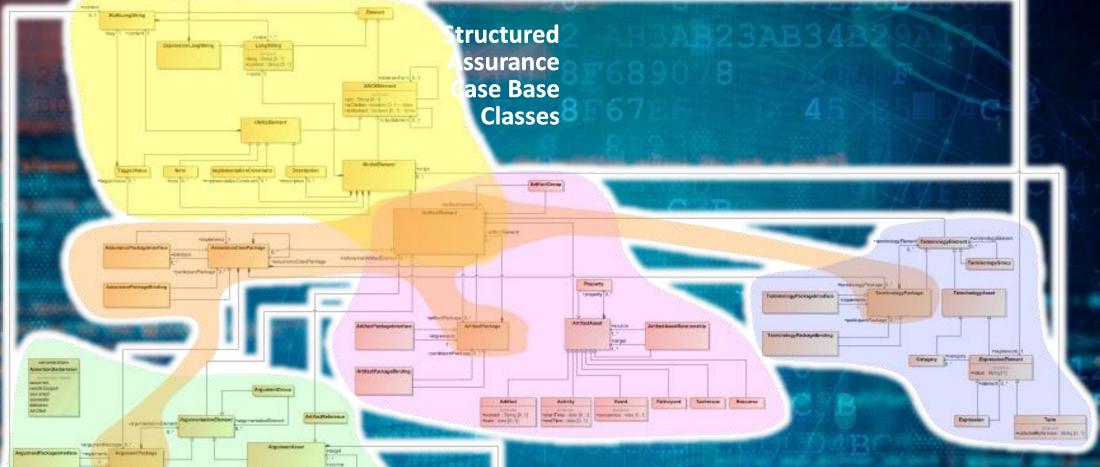


**Structured Assurance** 

**Packages** 

Case

# Structured Assurance Case MetaModel (SACM 2.2)



**Artifact Metamodel** 

Structured Assurance Case Terminology Classes

Argumentation Metamodel

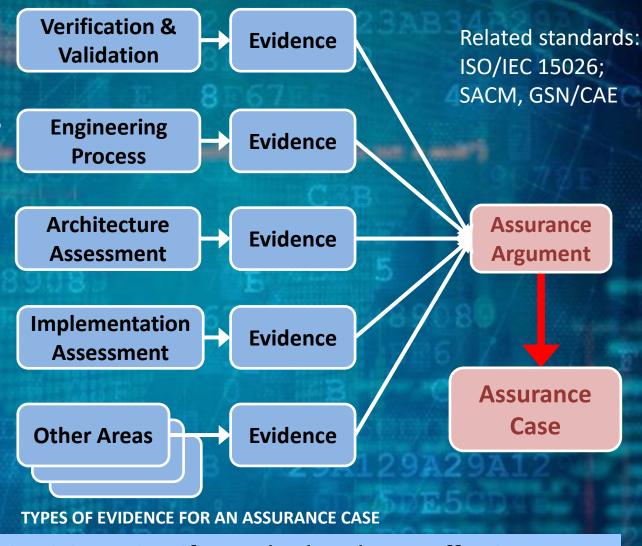
**MITRE** 

# **Establishing Assurance - Reducing Uncertainty**

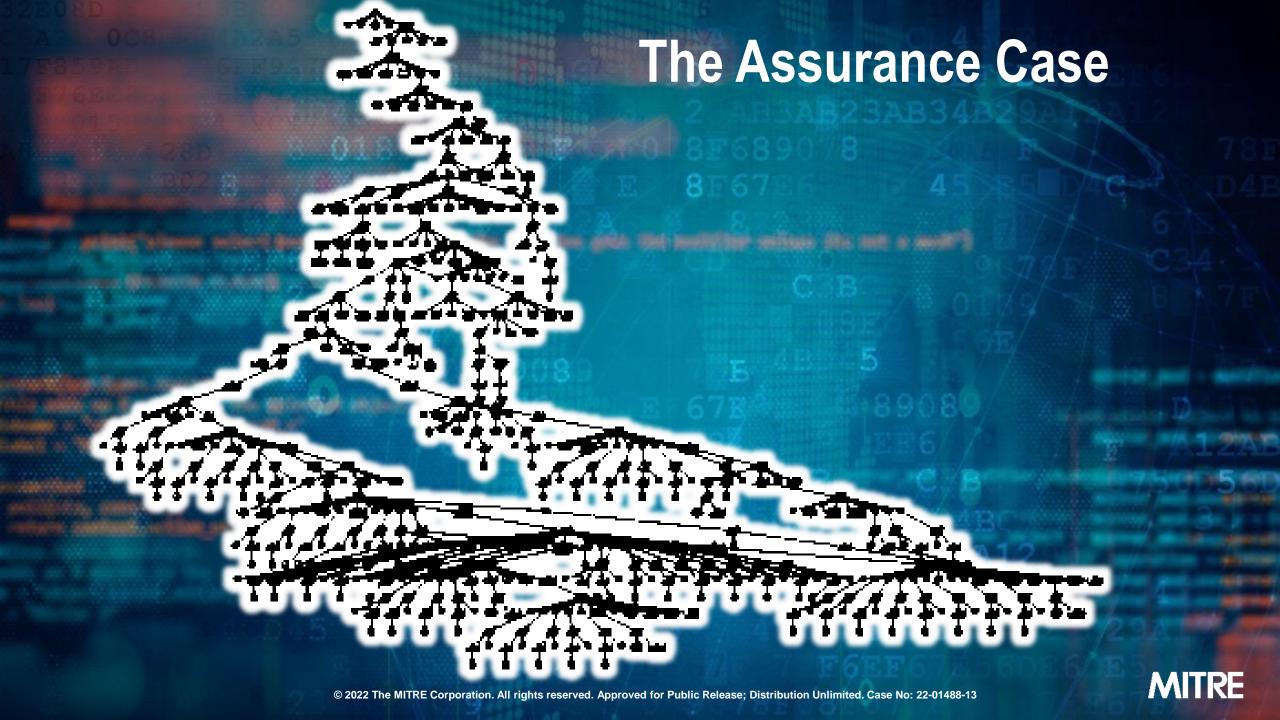
While Assurance does not provide additional security services or safeguards, it does serve to reduce the uncertainty associated with vulnerabilities resulting from

- Bad practices
- Incorrect & inefficient safeguards

The result of System Assurance is justified confidence delivered in the form of an Assurance Case

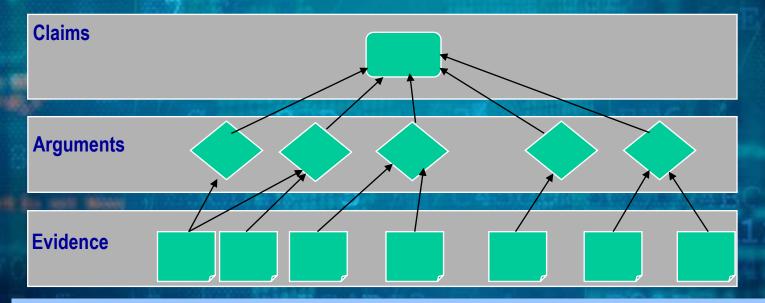


Confidence demands objectivity, scientific method and cost-effectiveness



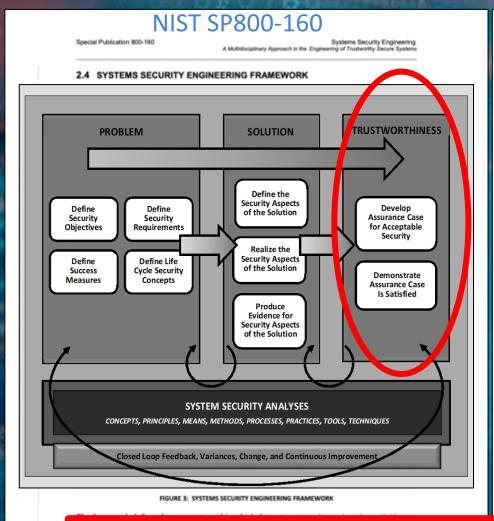
# Assurance and Evidence (NIST SP800-160)

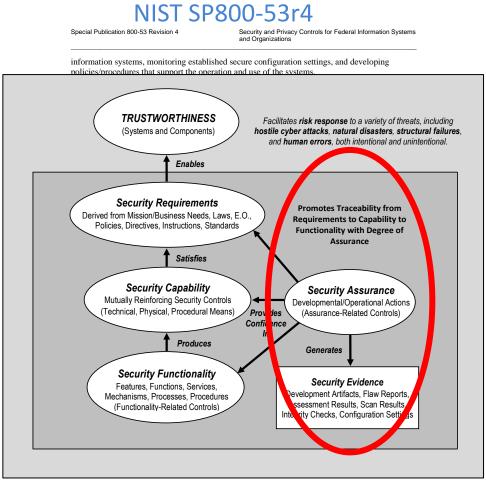
- Assurance is best grounded in relevant and credible evidence used to substantiate a claim
  - "the system is acceptably safe / secure"
- An assurance case relate claims and evidence
  - Via structured argumentation and argument patterns
  - Automated via assurance case tools



GSN & CAE: 15+ Years Aviation Safety

# Communicating Assurance to Gain Trust





ISO/IEC 15026-2 Assurance Case

**OMG Structured Assurance Case Metamodel (SACM)** 

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**MITRE** 

### Infusion Pumps Total Product Life Cycle

### **Guidance for Industry and FDA Staff**

Document issued on: December 2, 2014

The draft of this document was issued on April 23, 2010.

This document supersedes the "Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps," issued March, 1993.

OMB Control Number: 0910-0766 Expiration Page 5/31/2017

For questions regarding this document, please of Branch, Office of Device Evaluation at 301-796

For questions regarding safety assurance cases, Devices Branch, Office of Device Evaluation a richard.chapman@fda.hhs.gov.

For questions regarding pre-clearance inspection Ear/Nose/Throat, General Hospital, Infectious Compliance at 301-796-5770 or via email at free

For questions pertaining to manufacturer report 301-796-6104 or via email at <a href="mailto:sharon.kapsch@f">sharon.kapsch@f</a>



· The technological features of the devices.

You should describe how any differences in technology may affect the comparative safety and performance of your device.

#### 5. Safety Assurance Case

Infusion pump \$10(l) submissions typically include changes or modifications to software, materials, design, performance, or other features compared to the predicate. Accordingly, FDA expects that most new devices (as well as most changed or modified devices) will have differences in technological characteristics from the legally marketed predicate device even if sharing the same intended use. Under section \$15(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), determinations of substantial equivalence will rely on whether the information submitted, including appropriate clinical or scientific data, demonstrate that the new or modified device is as safe and effective as the legally marketed predicate device and does not raise different questions of safety and effectiveness in comparison to the predicate device.

In determining whether your new, changed, or modified infusion pump is substantially equivalent, FDA recommends that you submit your information through a framework known as a safety assurance case.\*

The safety assurance case (or safety case) consists of a structured argument, supported by a body of valid scientific evidence that provides an organized case that the infusion pump adequately addresses hazards associated with its intended use within its environment of use. The argument should be commensurate with the potential risk posed by the infusion pump, the complexity of the infusion pump, and the familiarity with the identified risks and mitigation measures.

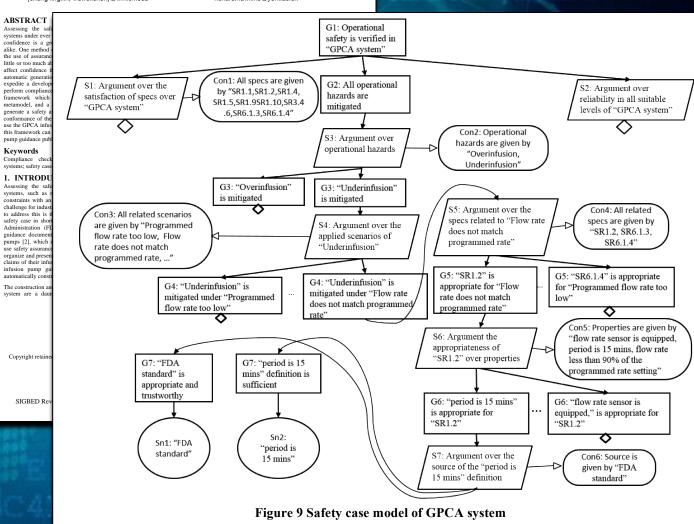
Second FDA's analysis of these devices, FDA expects that most changes or modifications to infusion pumps could significantly affect the safety or effectiveness of the devices and would therefore require submission of a new 510(3), See 21 CFR 80.78 (1/8), Nose that a change to the intended use or technology of a 510(b)-cleared device may render the device not substantially equivalent (NSE) to a legally marketed predicate. For detailed information about substantial equivalence and 510(s) submissions, refer to the FDA guidance entitled. The 510(s) Frogram: Evaluating Substantial Equivalence in Promarket Notifications (510(s)).

(http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf). Any such device may thus be a class III device and require a premarket approval application (PMA), unless the device is reclassified under section 513 of the Federal Food. Drue, and Cosmetic Act.

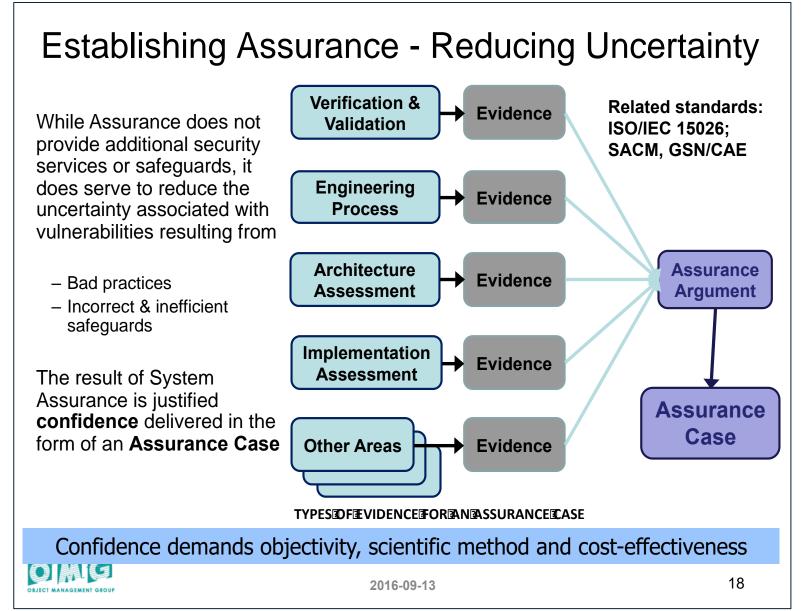
For more information about assurance case reports, see, for example: Graydon, P., J. Knight, and E. Strutik,
"Assurance Based Development of Critical Systems," Proc. of 37" Annual International Conference on Dependable
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A Step-Dy-Step Approach," Proc. of Workshop on Assurance Cases for Security – The Metrics Challenge, Dependable
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Medical Devices," Camegie Mellon Software Engineering Institute, October 2009, Hawkims, Richard, et. al., A New
Approach to Certain Clear Safety Arguments, Safety-critical Systems Symposium, Southampton, U.K. Februsary
2011; U.K Ministry of Defence, Defence Standard 00-56, Safety Management Requirements for Defence Systems –
Part 1 and Part 2, June 2007.

#### Support for Safety Case Generation via Model Transformation

Chung-Ling Lin, Wuwei Shen Department of Computer Science Western Michigan University Kalamazoo, MI, USA {chung-ling.lin, wuwei.shen}@wmich.edu Richard Hawkins
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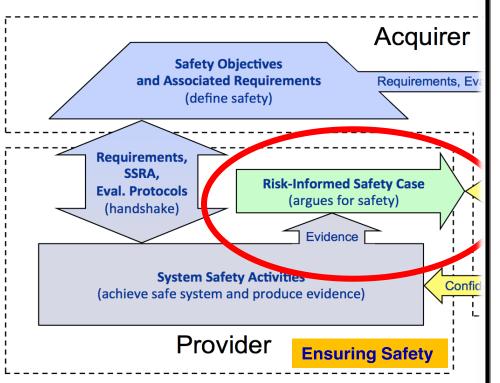


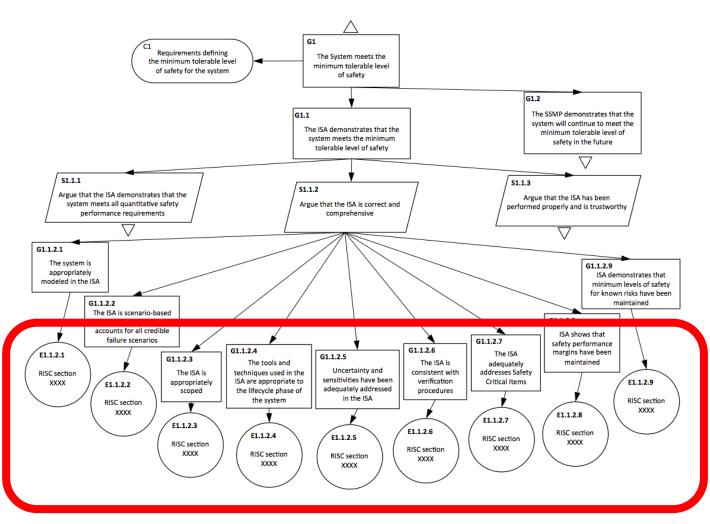
# Inspectable, Composable, Efficient, Evidence-base Assurance Utilizing the Assurance Case





NASA System Safety Framework (cont.)

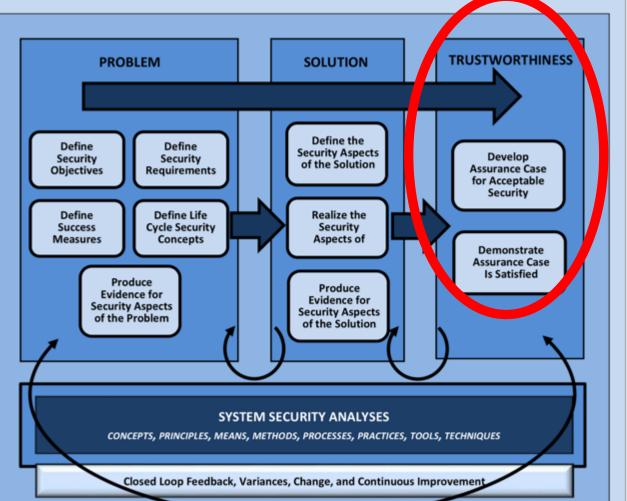


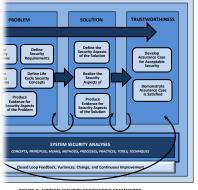




#### 2.4 SYSTEMS SECURITY ENGINEERING FRAMEWORK

The systems security engineering framework [McEvilley15] provides a conceptual view of the key contexts within which systems security engineering activities are conducted. The framework defines, bounds, and focuses the systems security engineering activities and tasks, both technical and nontechnical, towards the achievement of stakeholder security objectives and presents a coherent, well-formed, evidence-based case that those objectives have been achieved. 26 The framework is independent of system type and engineering or acquisition process model and is not to be interpreted as a sequence of flows or process steps but rather as a set of interacting contexts, each with its own checks and balances. The systems security engineering framework emphasizes an integrated, holistic security perspective across all stages of the system life cycle and is applied to satisfy the milestone objectives of each life cycle stage. Figure 3 provides an overview of the y engineering framework and its key components.





defines three contexts within which the systems security engineering activities are se are the problem context, the solution context, and the trustworthiness context. three contexts helps to ensure that the engineering of a system is driven by a plete understanding of the problem articulated in a set of stakeholder security

ASA111.

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## Systems Security Engineering Considerations for a Multidisciplinary Approach in the

Engineering of Trustworthy Secure Systems

#### **RON ROSS**

Computer Security Division National Institute of Standards and Technology

> MICHAEL McEVILLEY The MITRE Corporation

#### **JANET CARRIER OREN**

Legg Mason

This publication is available free of charge from: https://doi.org/10.6028/NIST.SP.800-160

#### November 2016

INCLUDES UPDATES AS OF 01-03-2018: PAGE XIII



U.S. Department of Commerce Penny Pritzker, Secretary

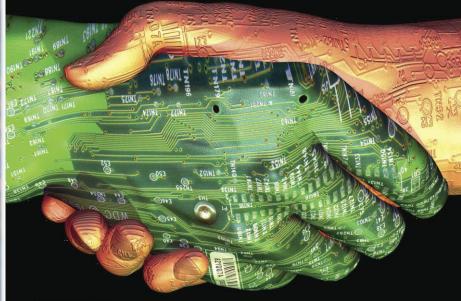
National Institute of Standards and Technology Willie May, Under Secretary of Commerce for Standards and Technology and Director





## **Special theme: Trustworthy Systems of Systems**

Safety & Security Co-engineering



#### Also in this issue:

"Trustworthy Systems of Systems -

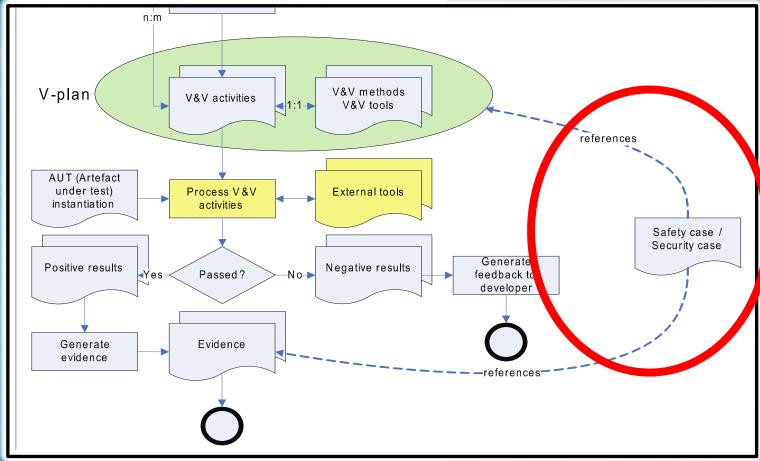
PaaSage and OW2 Announced Platform

## **European Research Consortium for** Informatics and Mathematics (ERCIM)

Workflow Engine for Analysis, Certification and Test of Safety and Security-Critical Systems

by Christoph Schmittner, Egbert Althammer and Thomas Gruber

Certification and Qualification are important steps for safety- and security-critical systems. In Cyber



ERCIM NEWS 102 July 2015



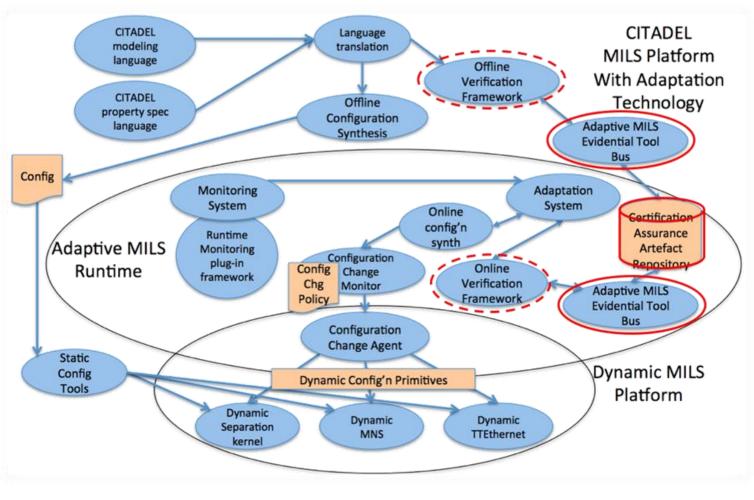


Figure 1: AM-ETB role in CITADEL



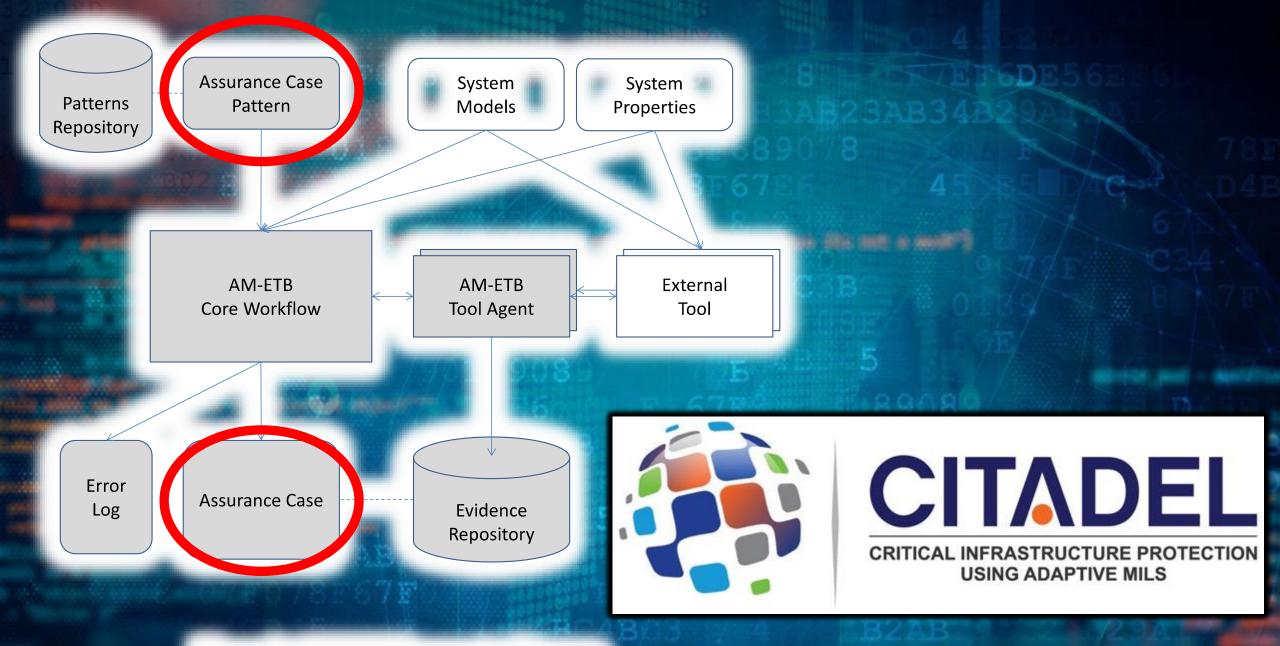


Figure 2: AM-ETB System Architecture





CONSORTIUM

# The Assurance Case













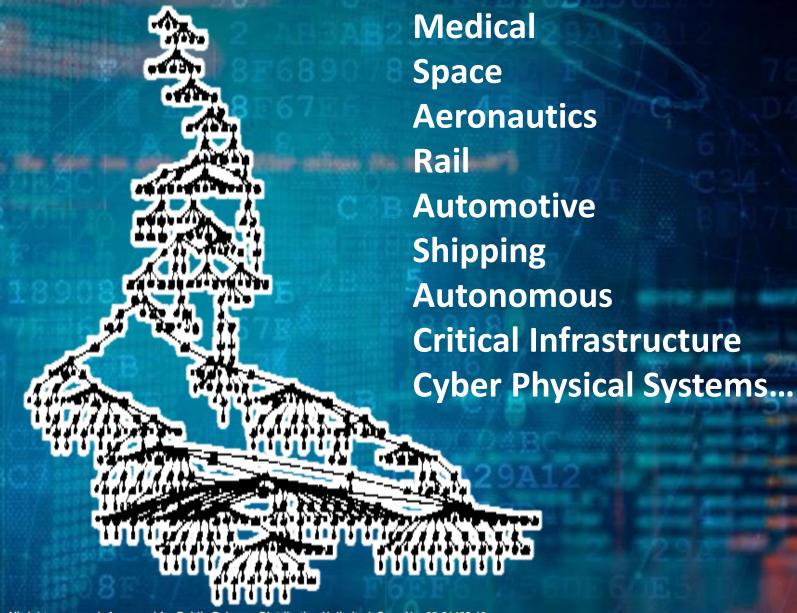


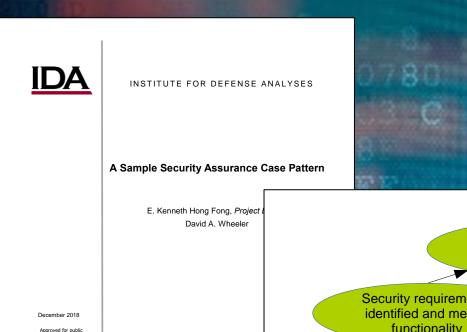






Dependability Engineering Innovation for Cyber Physical **Systems** 





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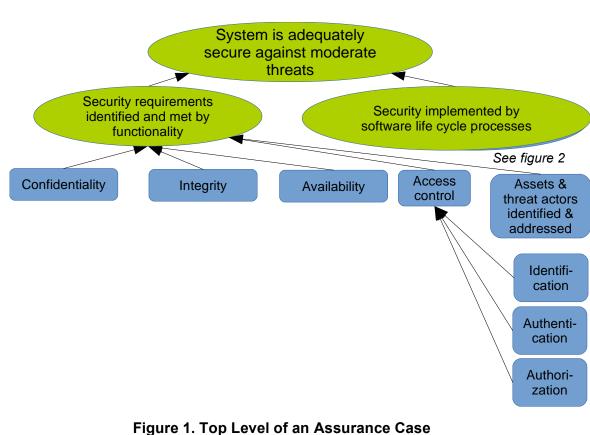
IDA Paper P-9278

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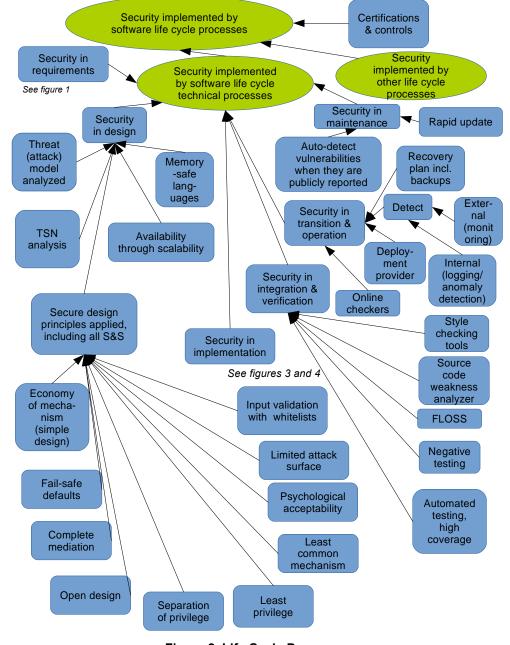
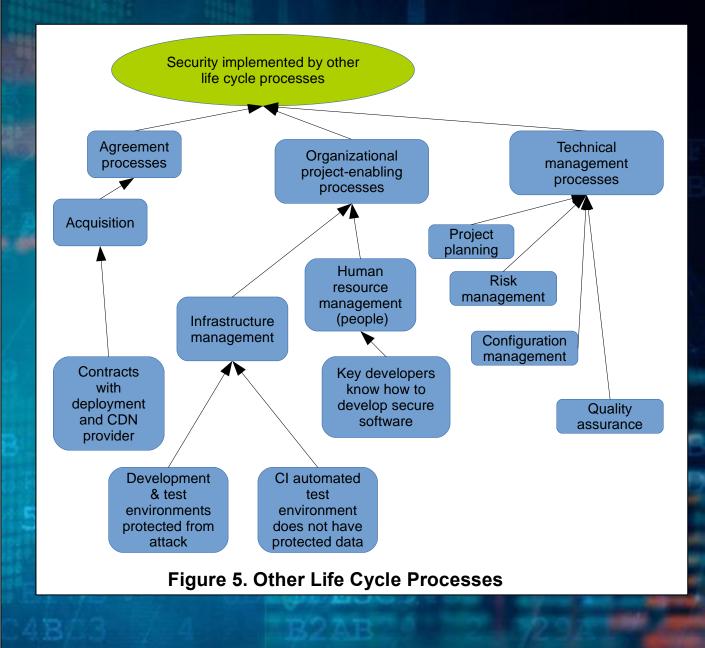
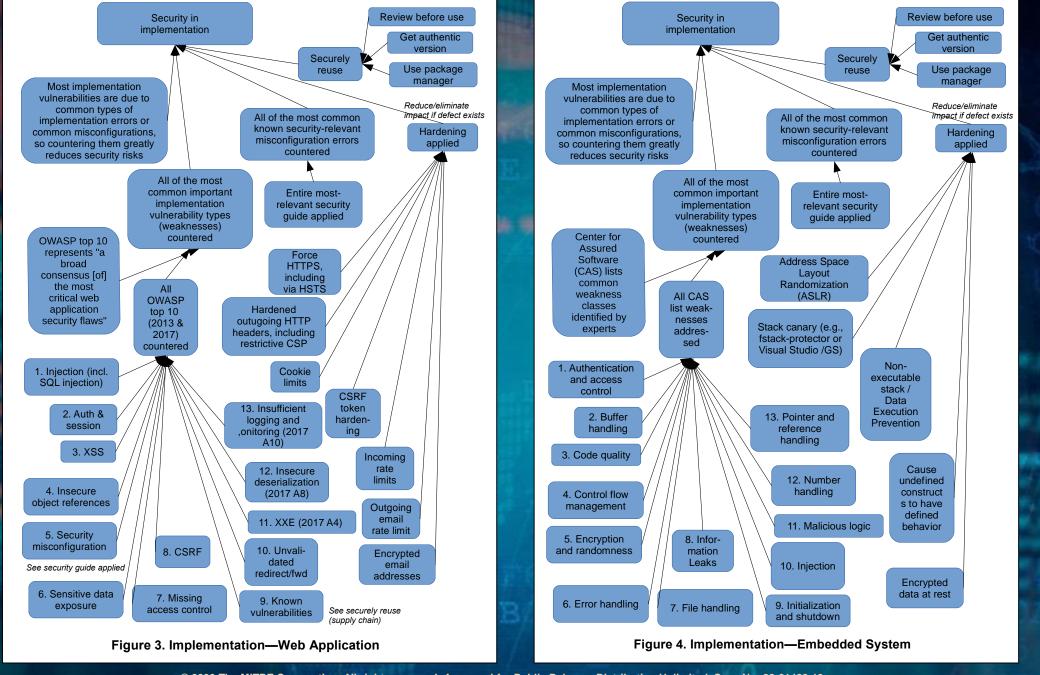
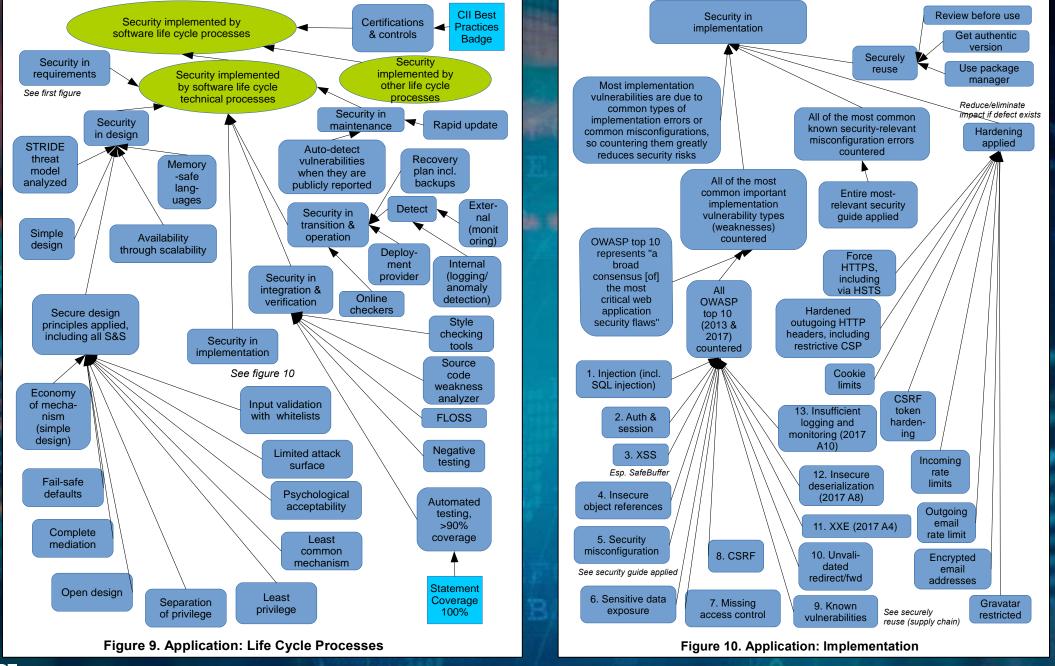


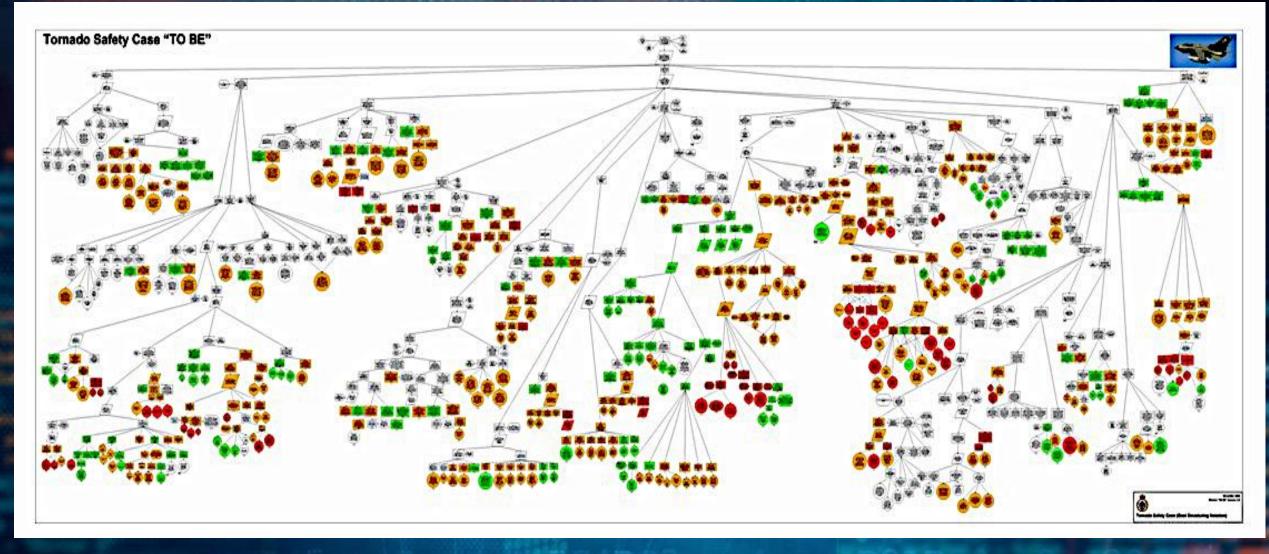
Figure 2. Life Cycle Processes







# **Tornado Operational Safety Case**



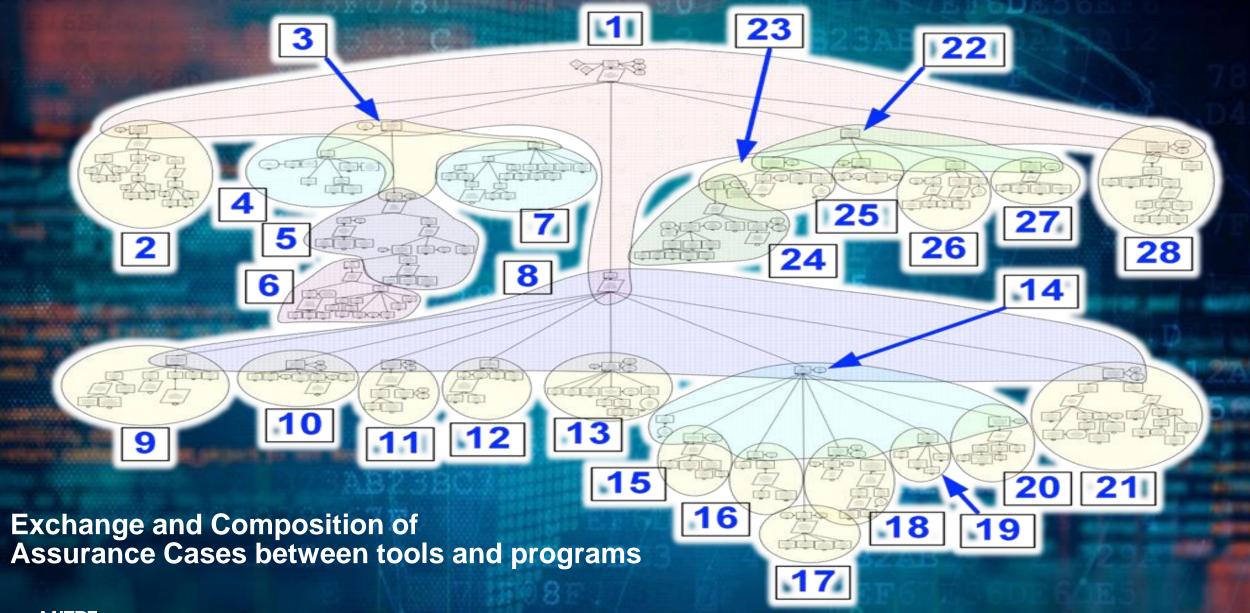
Apportionment of Ownership:

White = Generic, Green = Air Command, Orange = DE&S, Red = Contractors

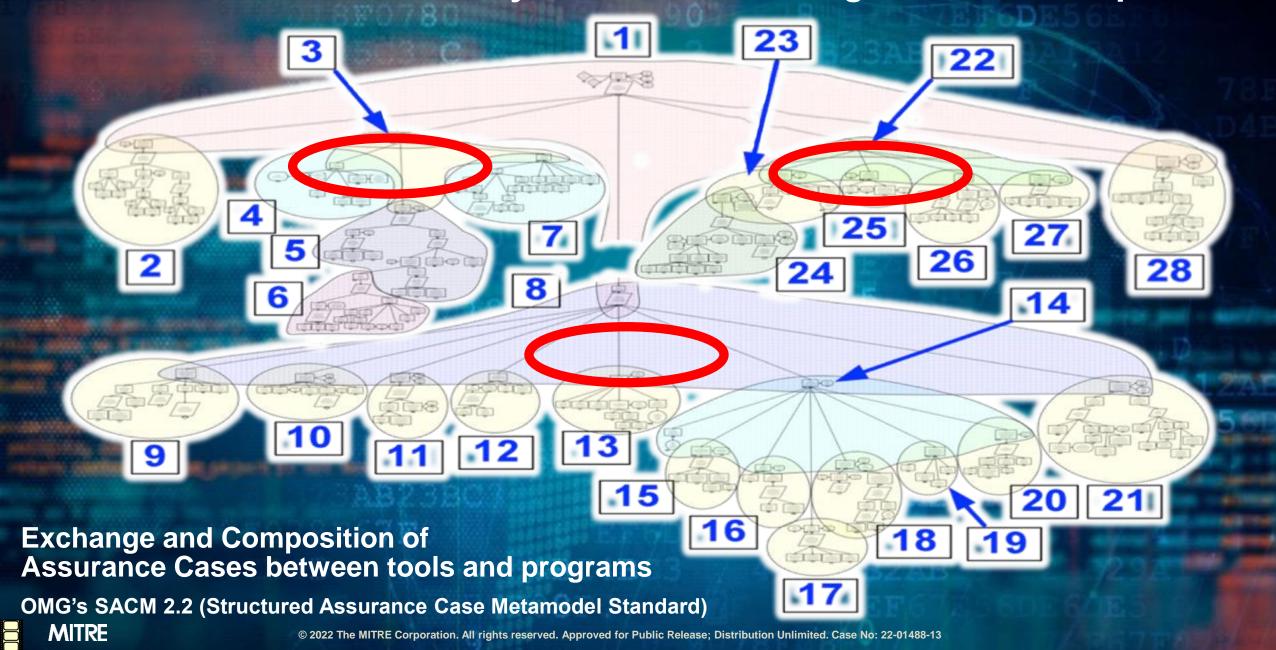
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# The Assurance Case for a System Builder using Assured Components



# The Assurance Case for a System Builder using Assured Components

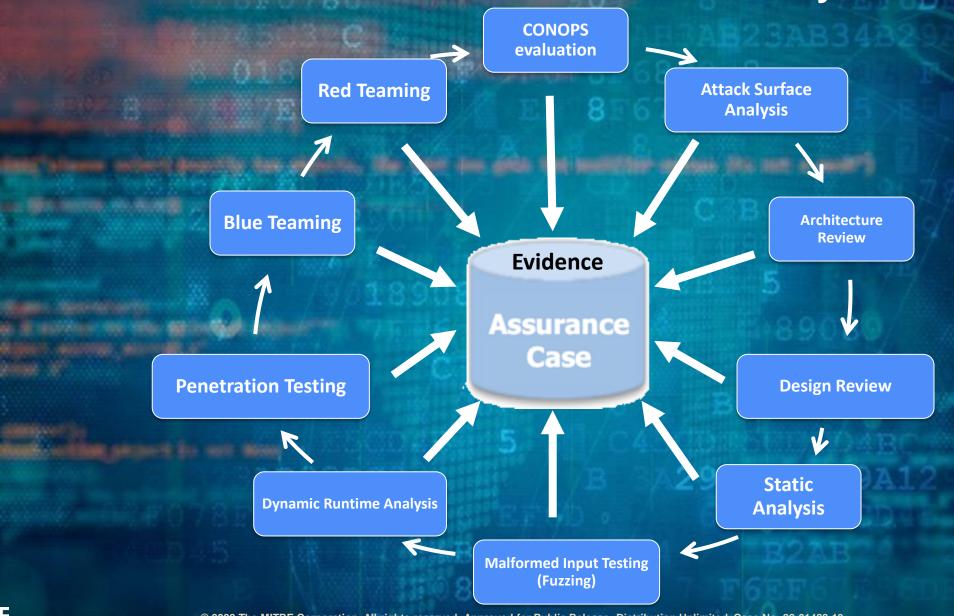


## Utilizing Appropriate Detection Methods to Collect Evidence to Gain Assurance...

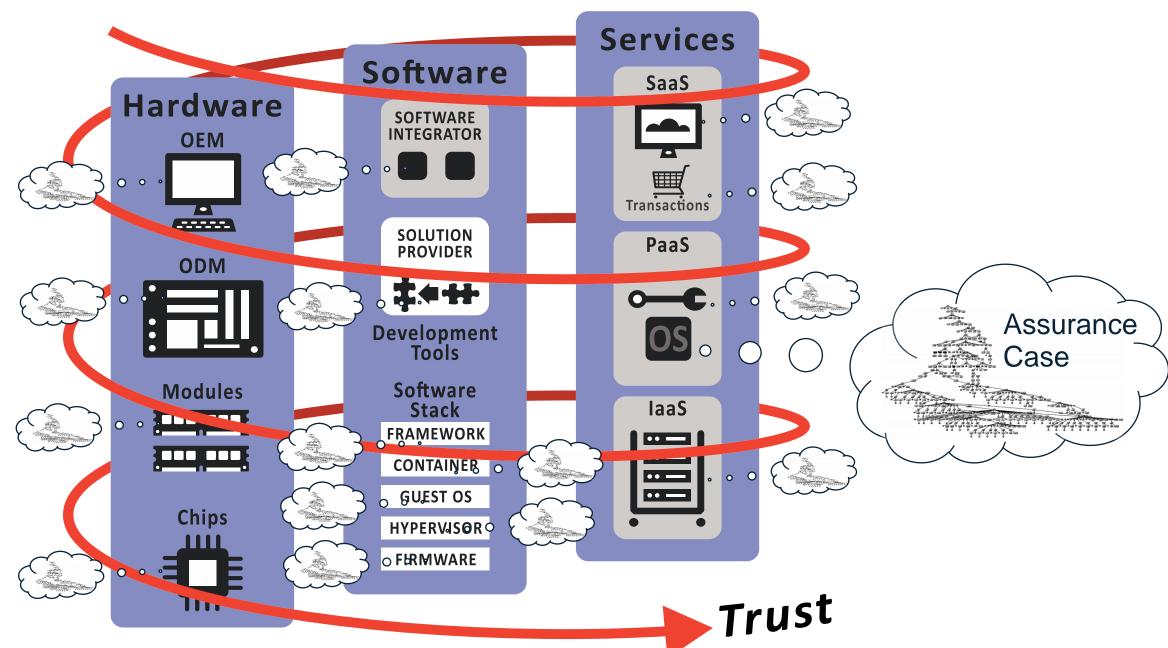
Coverage **Detection Methods Artifacts** Design Review **CONOPS Code Review** Requirements **Attack Surface Analysis** Architecture Static Analysis Tool A Design **Process** Static Analysis Tool B Code Dynamic Analysis Tool C **Binary Fuzz Testing Running Binary** 000000000000 **Pen Testing Environment of System Use of Mission Software Blue Teaming Red Teaming** MITRE © 2022 The MITRE Corporation. All rights reserved. Approved for Public Release; Distribution Unlimited. Case No: 22-01488-13

Most **Important** Quality Issues

# The Multiple Detection Methods are Sources of Assurance Evidence from Across the Lifecycle

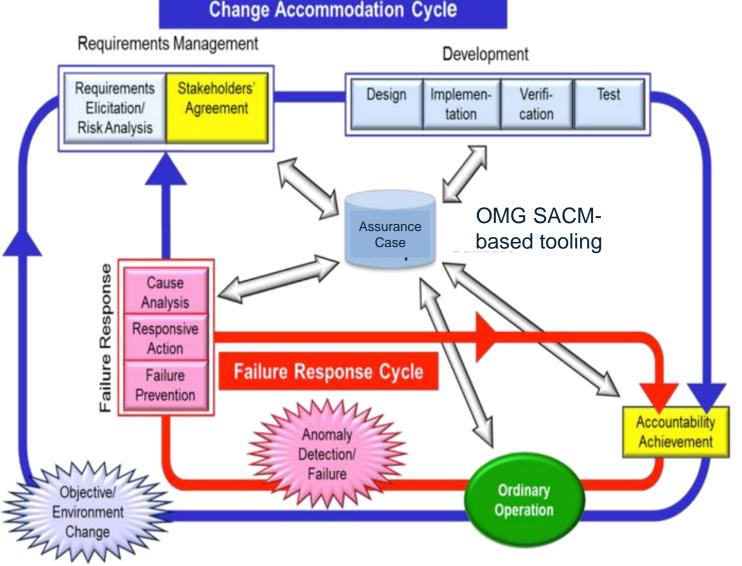


### TRUST RELATIONSHIP BETWEEN COMPONENT BUILDERS - FUTURE



# Open Group's Dependability Framework (O-DA): Implied Reqts-Design/Development/Evaluation

- Using an Assurance
   Case Model to capture
   (as claims) the
   behaviors the resultant
   system is meant to have
- Tying the evidence developed/collected to the supported claims as an ongoing part of creating and maintaining the system

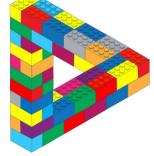




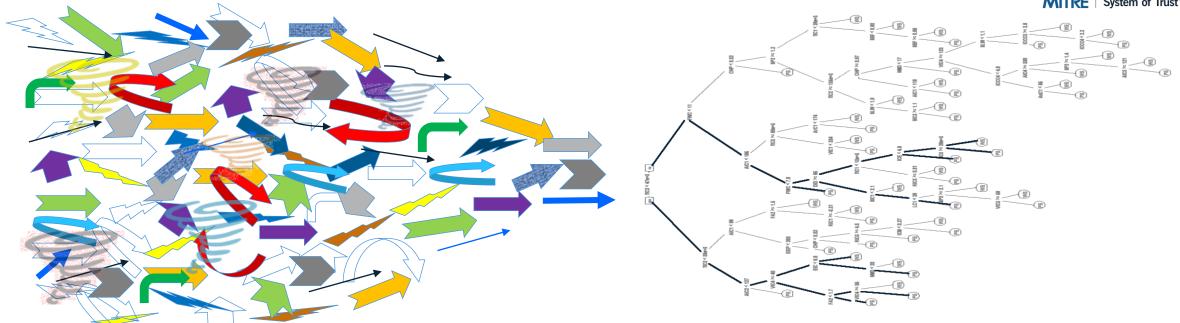
# Supply Chain Security (SCS) System of Trust (SoT)

"What Supply Chain Risks to Manage?"

# SoT - a strategic, widely-adoptable, holistic, data-driven analysis platform to assess supply chain security risks



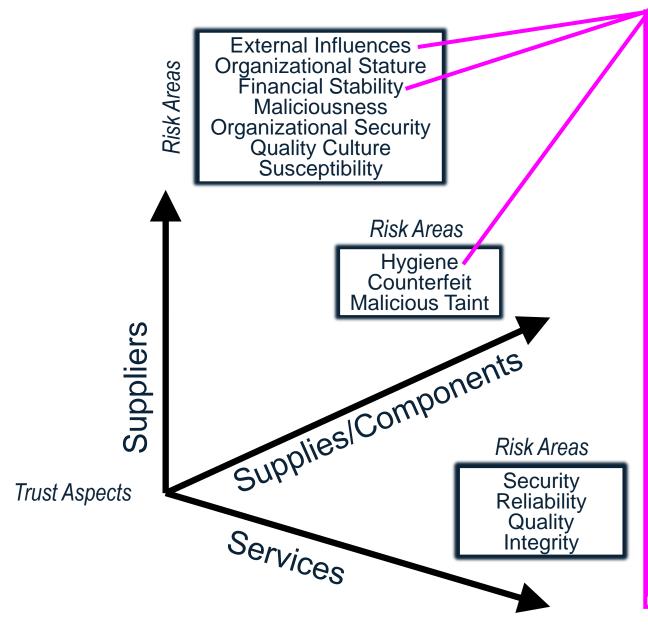
MITRE | System of Trust™



Address Chaos, Align & Organize

Simplify, Tailor & Use

## **Basis of Trust**



### Product Quality

- ICT Hardware Product Quality
- Product Quality Requirements
- Software Product Quality
  - Software Anomaly Control
  - Software Consistency
  - Software Design Simplicity
  - Software Provenance & Pedigree
  - 0 ...

### Product Resilience

- ICT Hardware Product Resilience
- Software Product Resilience

### Product Security

- ICT Hardware Product Security
- Inadequate protection for controlled unclassified information
- Information on product manufacturer information systems not backed up regularly
- Misconfigured access controls on product manufacturer information systems
- Sensitive information in digital form not encrypted while in physical transit either to or from product manufacturer
- Users of product manufacturer information systems do not receive cybersecurity training
- Weak identification and authentication controls on product manufacturer information systems
- ...



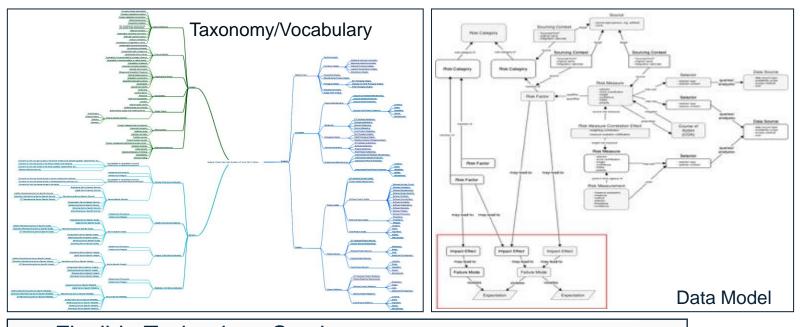
# MITRE Supply Chain Security System of Trust Risk Areas\* \*\*

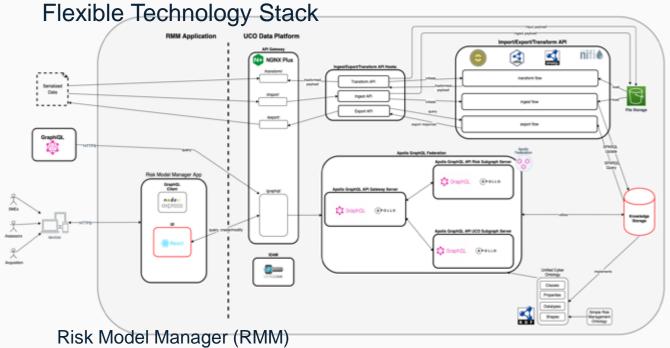
	Supply Ch						n lin Risks						
	Supplier Risks						1	Supply Risks		Services Risks			
xternal Influences	Financial Stability	Organizational Stature	Susceptibility	Quality Culture	Maliciousness	Organizational Security	Hygiene	Malicious Taint	Counterfeit	Integrity of Service Delivered	Quality of Service Delivered	Reliability of Service Delivered	Security of Service Delivered
Company foreign relationships with countries of concern	Questionable debt management	Corporate ownership reputation	Customers	Company has a low CMMI rating	Foreign Intelligence Service (FIS) influence	Concerns regarding facility access	Product quality	Facilities integrity	Copycat manufacturing	Service infrastructure pedigree	Service infrastructure pedigree	Service infrastructure pedigree	Service infrastructure pedigree
Company operational locations in countries of concern	Questionable financial stewardship	Diversity and inclusion	Industry sector	Internal company QC, SCRM policy & practice	Fraud and corruption	Concerns regarding software access	Product resilience	Functional integrity	Mislabeling	Service Infrastructure provenance	Service infrastructure provenance	Service infrastructure provenance	Service infrastructure provenance
Foreign registration/incorporation	Questionable future outlook	eographic concentration	Location	Subcontractor supply chain health / risk	Legal/law issues	Concerns regarding hardware access	Product security	Geopolitical integrity	Packaging integrity	Service specific integrity	Service specific quality	Service specific reliability	Service specific security
Geopolitical instability	Questionable profitability	Mergers & acquisitions frequency	Personnel		Sanction list status	Cyber threat activity		Logistics / transportation integrity	Technical authenticity				Susceptibility to manipulation of service infrastructure via physical access/touch
Key Management Personnel (KMP) and non- person entity relationships of concern	Vulnerability of financial stability to foreign influence	Natural disasters	Technical susceptibility			Data security status		Maintenance integrity	Unsanctioned manufacturing				Susceptibility to manipulation of service infrastructure via remote/virtual access/touch
National corruption	Vulnerability of financial ability to market factor					Type/ level /frequency of security training		Manufacturing process integrity					
National governance	Vu nerability to takeover	Sustainability				Vulnerabilities		Packaging integrity					
Organization ownership and control								Reputational integrity					
Politically Exposed Persor (PEPs) in corporate leadership								Supply chain integrity					
Political vulnerability			MITE	RE   System o	of Trust™								
Transparency of	MITPE's Supply Chain Security System of Trust IN												

MITRE's Supply Chain Security System of Trust™ https://www.mitre.org/publications/technical-papers/trusting-our-supply-chains-a-comprehensive-data-driven-approach



<sup>\*</sup> Supply Chain Security Top 75 Risk Areas Levels 1-4
\*\* System of Trust Expanding to Pharma, Food, and other types of Products



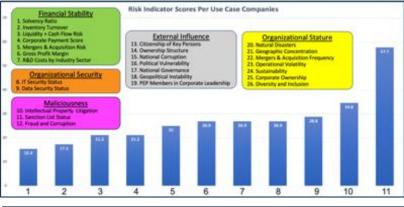


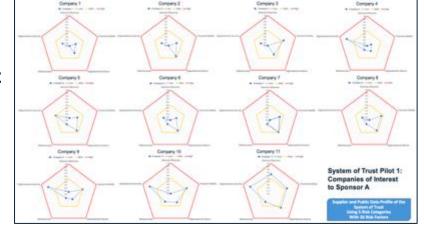
Piloting
11, 3, 1, 6,
22, 12, ...

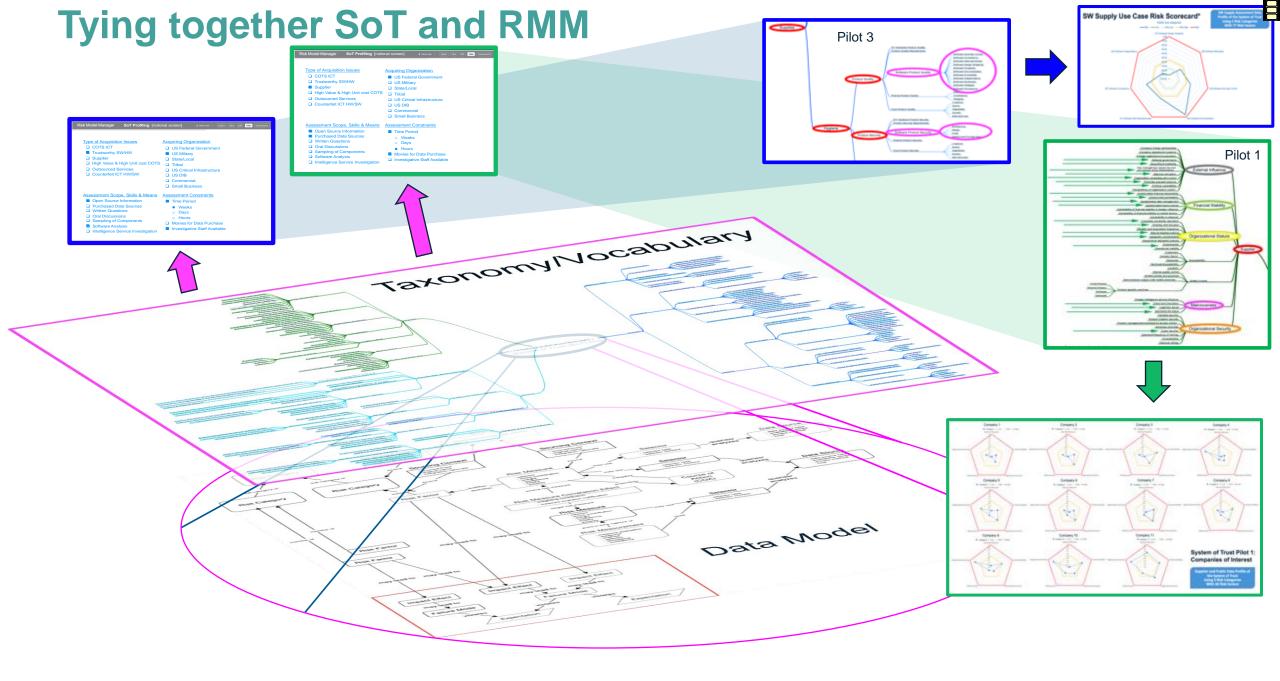
Export to Spreadsheet for "Offline" Assessment













# System of Trust – Addressing Supply Chain Security



MITRE | System of Trust™ Overview SoT Framework Pilot Results Resources News & Calend



### **Supply Chain Security**



Industry, government, and academia are putting increased focus on the need for trustworthy supply chains, trustworthy partners, and trusted systems globally. A reliable path to an actionable understanding of the risks that can impact the trustworthiness of supplies, suppliers, and services is essential.

The <u>System of Trust Framework</u> aims to provide a comprehensive, consistent, and repeatable supply chain security <u>risk assessment</u> process that is customizable, evidence-based, and scalable, and will enable all organizations within the supply chain to have confidence in each other, service offerings, and the supplies being delivered.

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https://sot.mitre.org

https://www.youtube.com/watch?v=PX0xzkfKSVA



Dependability Engineering Innovation for Cyber Physical Systems (DEIS) http://www.deis-project.eu/dissemination/

"Assuring Trustworthiness in an Open Global Market of IIoT Systems via Structured Assurance Cases"

https://www.iiconsortium.org/news/joi-articles/2018-Sept-Jol\_Assuring\_Trustworthiness-FINAL2.pdf

Questions?

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