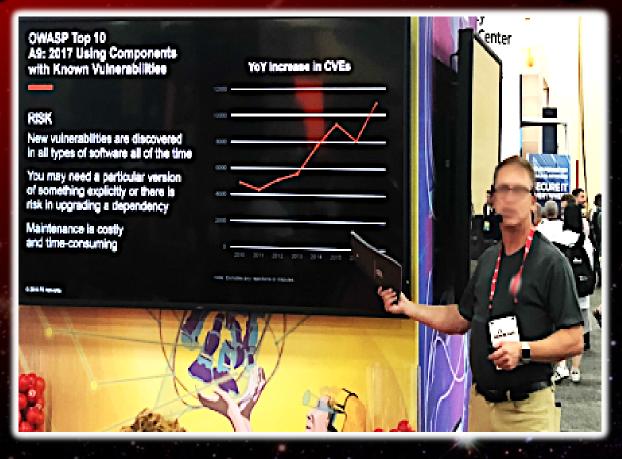
Visibility & Control: Addressing Supply Chain Challenges to Trustworthy Software-Enabled Things

Robert A. Martin

Sr. Secure Software & Technology Prin. Eng. Trust & Assurance Cyber Technologies Dept. Cyber Solutions Technical Center





IIC Forum | Long Beach, CA



Everything is Becoming Software-Enabled and Connected, Either through Task Dependency, Supply Chain, or Information Flow

Today Your System is:

- attackable or
- susceptible to a hazard...

When this Other System gets subverted through:

- an un-patched vulnerability;
- a mis-configuration;
- an application weakness;
- a counterfeit item;
- tainted software or hardware; or
- the system's susceptibility to a hazard...

We need to be assured that not only are our own systems trustworthy but also everything we depend upon...



How is Software-Enabled and Connected (aka Cyber) Becoming so Pervasive?

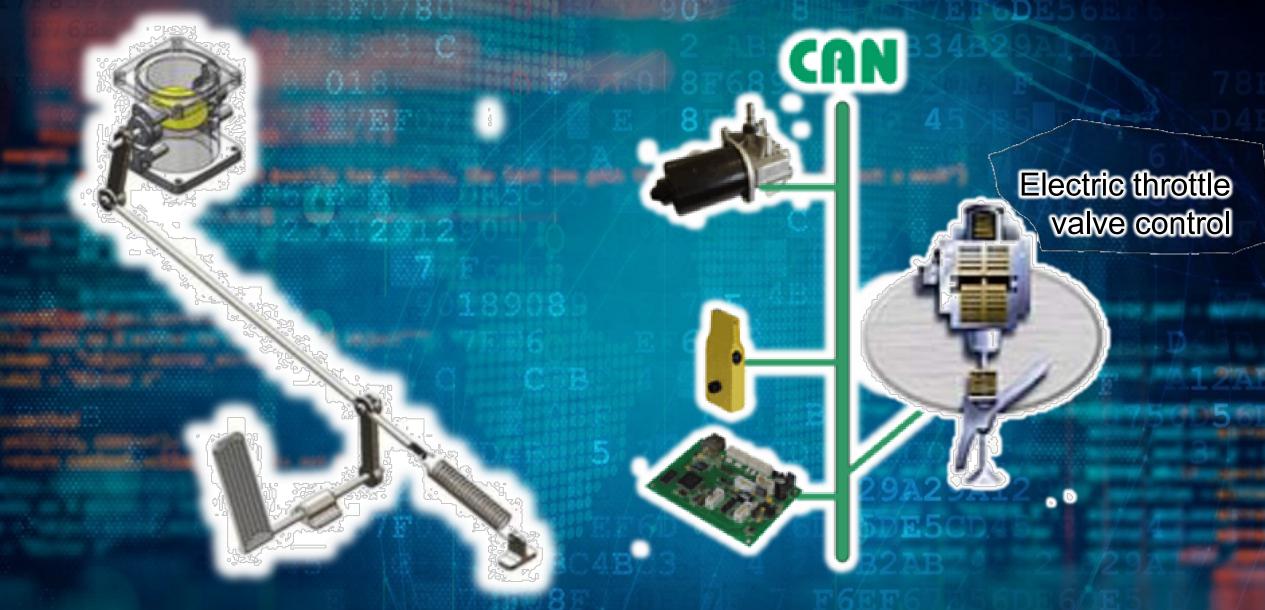
Context: 1976 Chevy Vega



The only software was behind the wheel - no microelectronics.

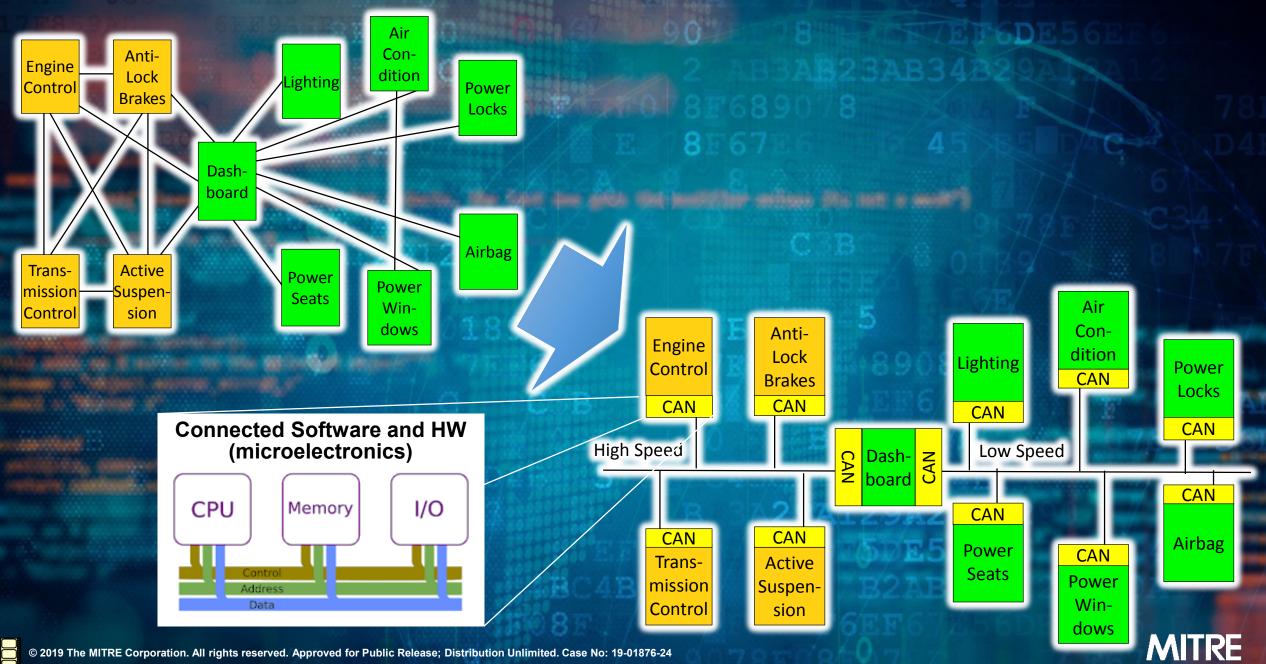


Critical Functions Migrated into Software & Microelectronics (SW/HW)

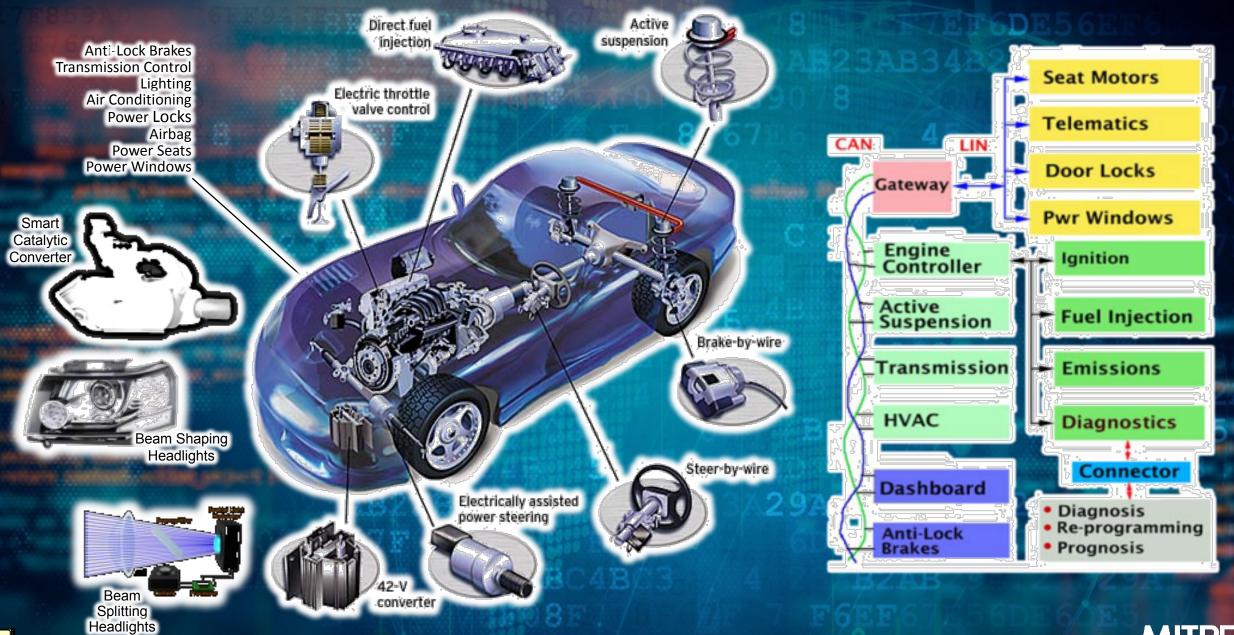




Control/Communication Transitioned from Point-to-Point Wiring to Network-based

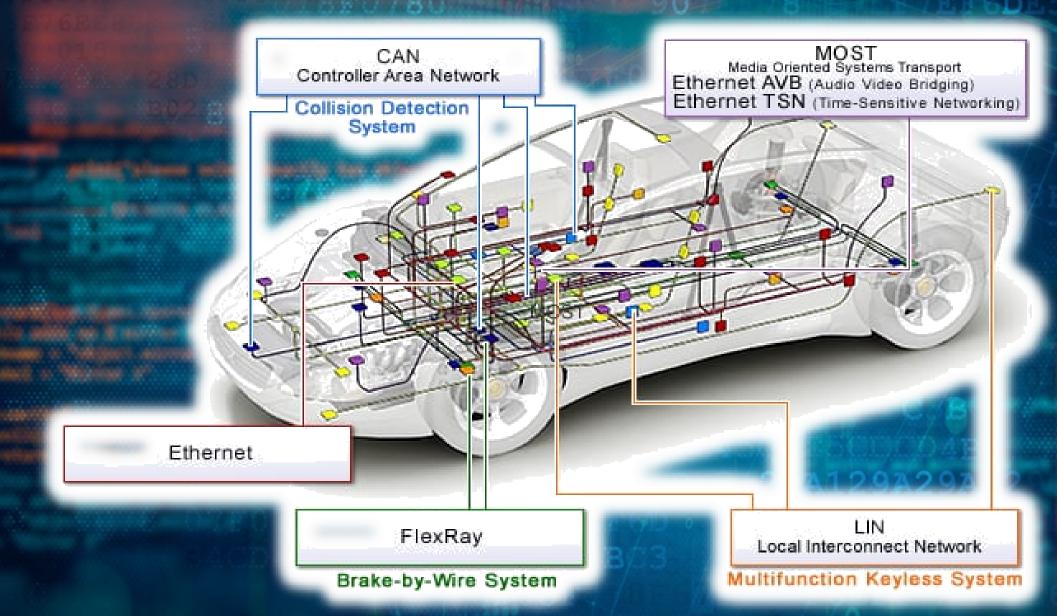


Critical Functions Are Migrating into Connected SW/HW



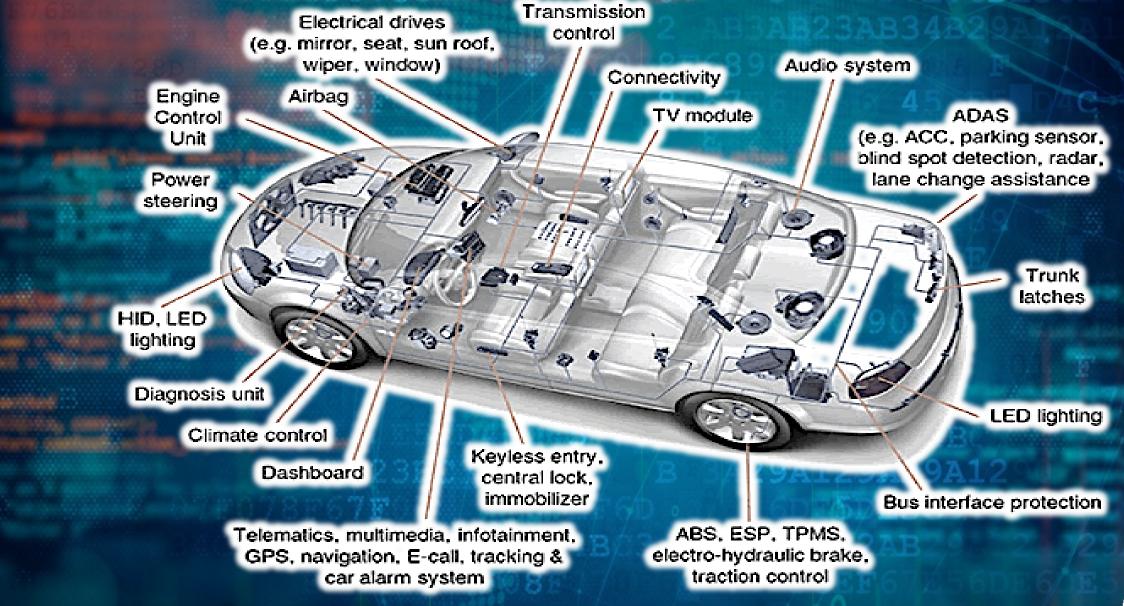


Multiple Types of Networks Are Appearing





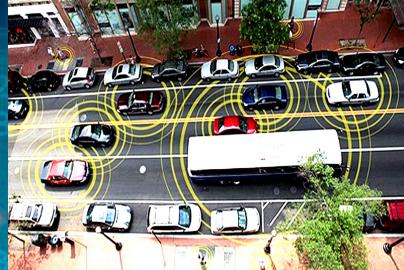
Many Critical Functions Now Need to be Updated and Sustained...



The Connectivity and Complexity of Connected Software-Enabled Systems is Still Expanding











All types of Enterprises are Facing these Same Changes...

Medical



Vehicles



Buildings



Aeronautics



Energy



Manufacturing



Shipping





These Changes Go Well beyond Traditional Information Technology...

Water Treatment



Status & Health Monitoring





Smart Munitions



Remote Management

Oil & Gas



Hydro Power & Dam Mngt





Secure Behavior

Reliable Behavior

Safe Behavior

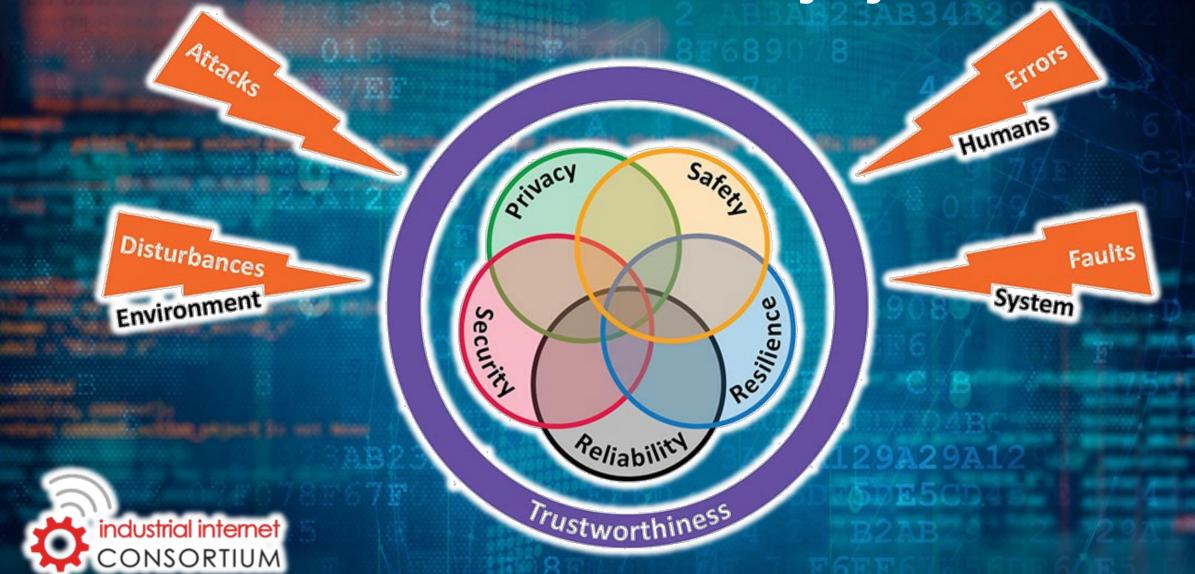
MIND THE GAP

Privacy Expectations

Resilient Behavior



Need Assurance of More Than Security – Need Assured Trustworthy Systems





Pervasiveness of connected SW & SW-enabled capabilities requires supply chain security skills / new awareness of SW risks

IT Risk

Operational Risk

Loss of data or capability

Loss of safety or reliability

Loss of property or lives

Scratch Built Software

Assembled Software

Majority of products built with no 3rd Party dependencies

Use of open source and 3rd party libraries, modules, frameworks, and services Multi-party software updating/patching

Traditional Computers

Software Enabled Everything

Servers databases

Desktops office apps

Laptops e-mail

Tablets browsers

Switches Routers

Healthcare
Aeronautics
Smart Energy
Oil & Gas
Microgrids

Implantable Medical
Smart Manufacturing
Water Treatment
Hydro Power
Smart Cities

Smart Munitions
Intelligent Vehicles
Intelligent Shipping
Dam Management
Building Management
Autonomous Systems

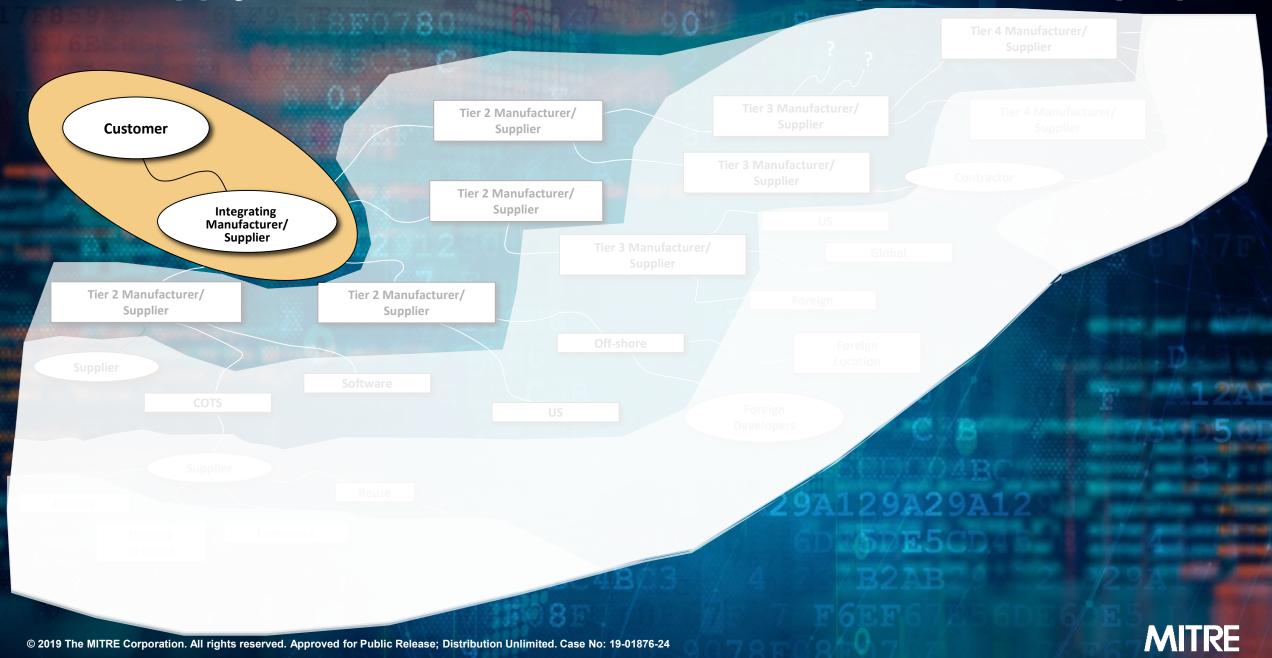




For Software-Enabled IIoT Version Control is Crucial



The Supply Chain for Software-Enabled Capabilities is Opaque



Market Transparency through "Software Bill of Materials"

- Third party components are a known systemic risk.
 - Transparency can drive tools and behavior to document risk, support mitigations, and drive better SW development practices.
- NTIA at Commerce launched an open, community-driven, crosssector "multistakeholder process" to promote software component transparency.
 - Understand the problem and define basics of SBOM
 - Develop use cases across sectors on how such data can be used, today and in the future.
 - Guidance on how to use existing standards to implement SBOM
 - Software ID tags (SWID)
 - Software Package Data Exchange (SPDX)
- First phase deliverable mid-November 2019
- More info or to join: afriedman@ntia.doc.gov



MANUNICATIONS & INFOR

NTIA Transparency Phase 1 Final Products

Framing Software Component
Transparency: Establishing a Common
Software Bill of Material (SBOM)

N TIA Multistakeholder Process on Software Component Transparency Framing Working Group 2019-11-12



Éamonn Ó Muirí https://flic.kr/p/48ds/iz https://areativecommons.org/licenses/by/2.0/legalcode Roles and Benefits for SBOM Across the Supply Chain NTIA Multistakeholder Process on Software Component Transparency Use Cases and State of Practice Working Group

Introduction

The Software Supply Chain

About this document: Goals and Methodology

Perspective: Produce Software

Reduce unplanned, unscheduled work

Reduce code bloat

Adequately understand dependencies within broader complex projects

Know and comply with the license obligations

Monitor components for vulnerabilities

End-of-life (EOL)

Make code easier to review

A blacklist of banned components

Provide an SBOM to a customer

Perspective: Choose Software

Identify potentially vulnerable components

A more targeted security analysis

Verify the sourcing

Compliance with policies

Aware of end-of-life components

Verify some claims

Understand the software's integration

Pre-purchase and pre-installation planning

Market signal

Perspective: Operate Software

Organization can quickly evaluate whether it is using the component

Drive independent mitigations

Make more informed risk-based decisions

Alerts about potential end-of-life

Better support compliance and reporting requirements

Reduce costs through a more streamlined and efficient administration

Ecosystem, Network Effects, and Public Health Benefits of SBOM

Accelerated Vulnerability Management

Survey of Existing SBOM Formats and Standards - Version 20191025

Survey of Existing SBOM Formats and Standards



Cred

NTIA Multistakeholder Process on Software Component Standards and Formats Working Group Final Version - 20191025

13 13

14

SOFTWARE COMPONENT TRANSPARENCY: HEALTHCARE PROOF OF CONCEPT REPORT

Drafted as part of a process convened by the National Telecommunications and Information Administration

October 1, 2019

Lowering Adoption Hurdles for SBOMs



- Agriculture and Food
- Energy
- Transportation
- Chemical Industry
- Postal and Shipping

- Water
- Public Health
- Telecommunications
- Banking and Finance
- Key Assets

End Users in Industry, Government, and Commerce

Sectors

- Medical Devices
- Merchandise
- Automobiles
- Trains
- Vessels/Boats
- Building Mngt Sys
- Software

















Assets Capabilities

Product & Service Suppliers

INTEGRATED DEVELOPMENT ENVIRONMENTS (IDEs)

CLOUD TOOLS

FRAMEWORKS

BUILD CHOREOGRAPHY

SOURCE CODE &
PACKAGE
REPOSITORIES

SOFTWARE COMPOSITION ANALYSIS

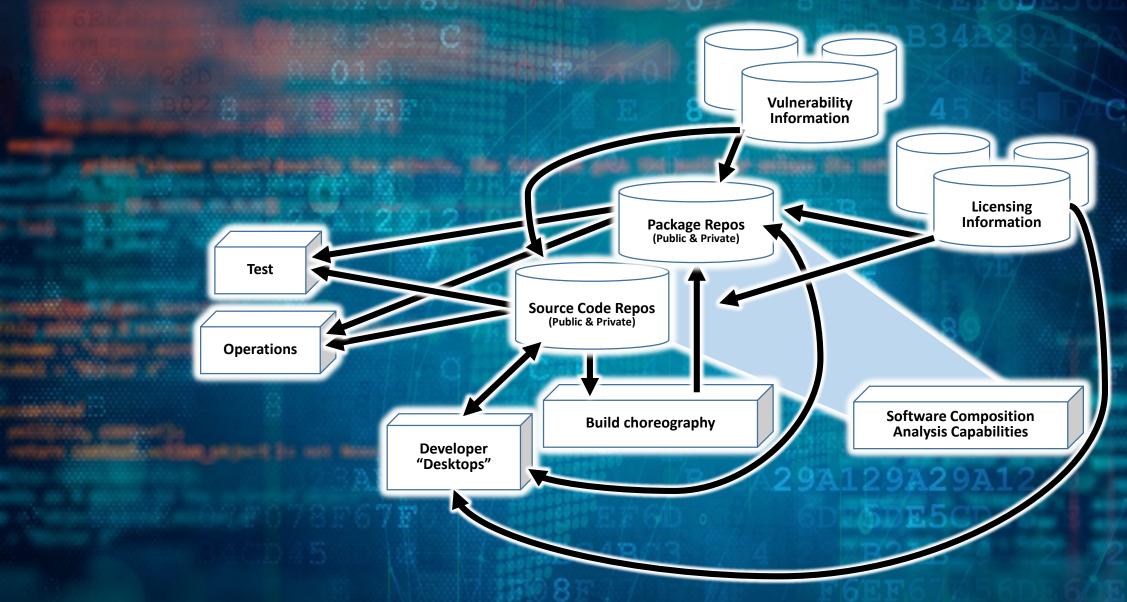
Tools & Capabilities for Software

Software Ecosystems Tool-to-Tool
SBOM Exchange
Standard effort





Ecosystem of SW Development, Integration, and Management Tools





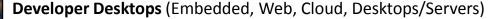
SW Development, Integration, and Management Tools

Source Code & Package Repositories

Amazon ECR, Assembla, Azure Container Registry, Beanstalk, Bitbucket, Codebase, Docker, GitHub, GitLab, Glitch, Google Container Registry, JFrog Artifactory, JFrog Xray, inedo, Kubernetes, Launchpad, Maven, Nexus (Sonatype), Phabricator, ProjectLocker, Repository Hosting, Savannah, SourceForge, SourceRepo, Subversion, and Unfuddle

Build & Build Choreography Capabilities

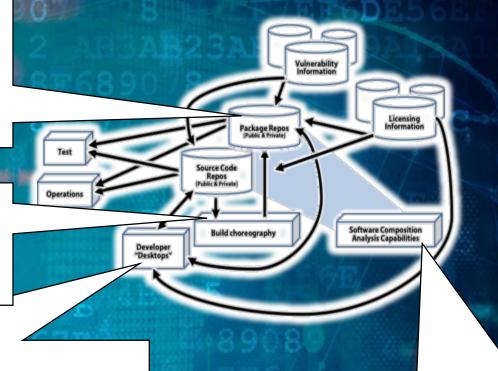
Ansible, Autorabit, Bamboo, Bitrise, Buildkite, Buildroot, CircleCl, CMake, CruiseControl, Final builder, GCC, Gitlab Cl, GoCD, Integrity, Jenkins, Strider CD, TeamCity, Terraform, Travis Cl, Urbancode, and Vagrant



IDEs: Android Studio, AppCode, Atom, BlueJ, CLion, Cloud9 IDE, Code Blocks, CodeCharge Studio, CodeLobster, CodePen, DataGrip, Eclipse, GoLand, IDLE, IntelliJ IDEA, LINX, Microsoft Visual Studio, MPLAB, NetBeans, PhpStorm, Pycharm, Rider, RubyMine, Spiralogics Application Architecture, WebStorm, Xcode, and Zend Studio

Frameworks: .NET, Angular, Ansible, Apache Spark, ASP.NET, Bootstrap, Chef, Cordova, CryEngine, Django, Drupal, Express, Flask, Flutter, Hadoop, HTML5 Builder, Laravel, Node.js, Pandas, Puppet, React Native, React.js, Ruby on Rails, Spring, TensorFlow, Torch/PyTorch, Unity D, Unreal Engine, Visual Online, Vue.js, and Xamarin

Cloud Tools: Azure, AWS CodeBuild, Cloud Foundry, Google Cloud Build, Kwatee, Pivotal, and Red Hat



Software Composition Analysis:

Black Duck Software Composition Analysis (Synopsys), CAST Highlight (CAST Software), Finate State, FlexNet Code Insite (Flexera), Ion Channel, Insignary, SourceClear, Sonatype, Snyk, and WhiteSource



Usage Scenarios for Tool-to-Tool SBoM

Refer, Transfer or Purchase (definition of what it is)

Pedigree (history of how it was produced)

Provenance (chain of custody of it)

Integrity (cryptographic basis of unalteredness)

Proper and Legal (conditions about its use)

Known Sw Vulns (known fixes are applied to it)

Assurance (safe-secure-resilient)

SBoM of a SW Service (SBoM of sw delivering service)

Supply Chain Sequence Integrity



Provenance and Pedigree

DEFINITIONS

- Provenance*
 - 1. The origin, or source of something
 - 2. The history of ownership of a valued object, or work of art, or literature
- Pedigree*
 - 1. A register recording a line of ancestors
 - 2. An ancestral line: lineage The origin and the history of something; broadly: background, history

CONFUSION

Many use "Provenance" for both meanings.

The provenance of a piece of data is both the custodianship as well as the lineage of processing and/or derivation that led to the piece of data.

*Definitions (from Merriam-Webster.com)





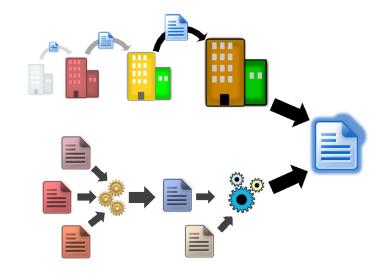
Separating Provenance and Pedigree

Provenance

Captures *chain of custody* of an Artifact,
Document or
Record

<u>Pedigree</u>

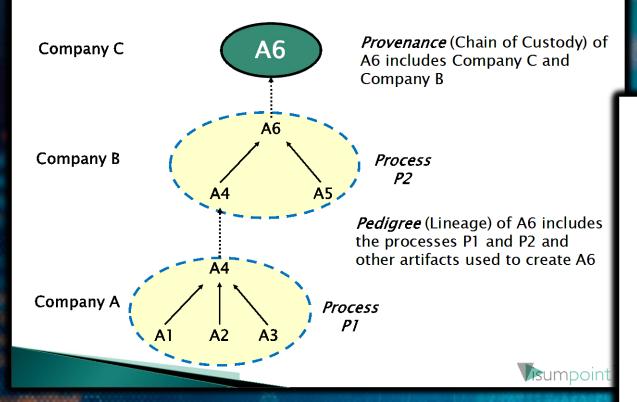
Captures the history of how an Artifact or Document was produced or derived







Combined Pedigree & Provenance





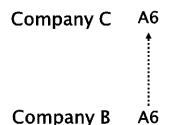
Separating Pedigree & Provenance

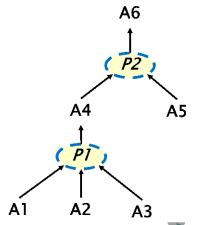
Provenance and *Pedigree* provide a basis on which to reason about the *trustworthiness* of an artifact or document

Provenance (Chain of Custody)



Pedigree (Lineage)









The Path to Code Provenance at Uber

April 17, 2019

Uber

Code Provenance

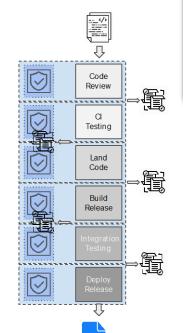
Ensuring we have a **verifiable attestation** of the **origin of all code** running in production so that we can have a **root of trust** as we move forward to **defining** and **enforcing** a collection of **policies** throughout the different stages of the **software development process**.



Code Provenance

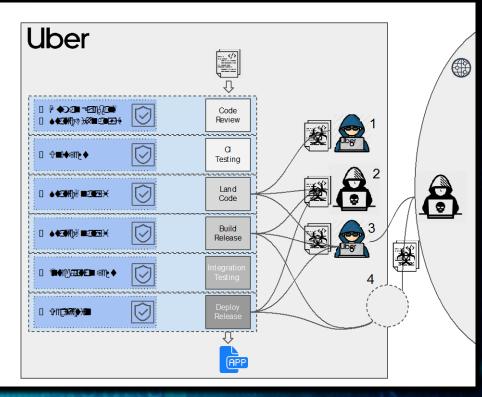
What do we get out of all this?

- "Chain of custody" for all code landing in production releases
- Enabling response in the event that anything goes awry
- Flexible, enforced policies for what code is allowed to land in production releases



Code Provenance

What are we protecting against?





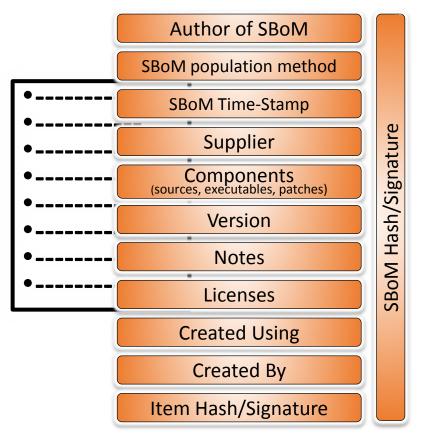


Usage Scenarios and Tool-to-Tool SBOM candidate elements

Usages

Refer, Transfer or Purchase (definition of what it is) Pedigree (history of how it was produced) Provenance (chain of custody of it) Integrity (cryptographic basis of unalteredness) **Intellectual Property** Constraints **Known SW Vulns** 6 (known fixes are applied to it) Assurance (secure-safe-resilient) SBoM of a SW Service (SBoM of sw delivering service) 9 Supply Chain Sequence Integrity

SBoM elements



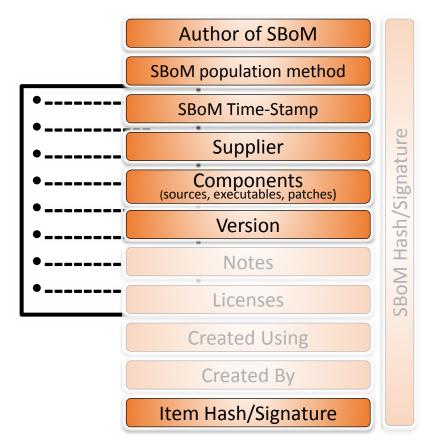
Correlated Info



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Integrity

SBoM elements

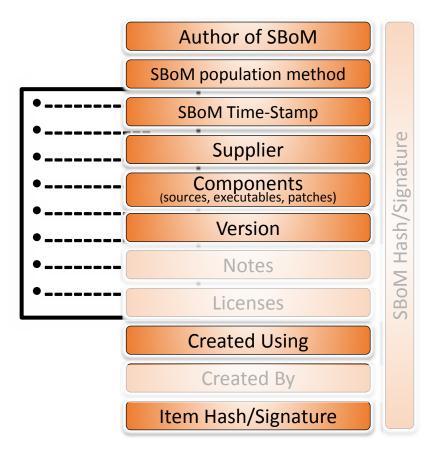


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SBoM elements

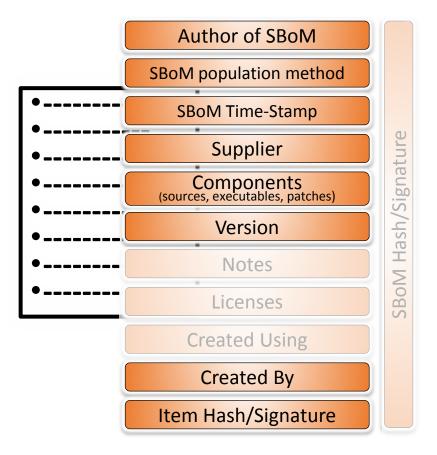


Correlated Info



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SBoM elements

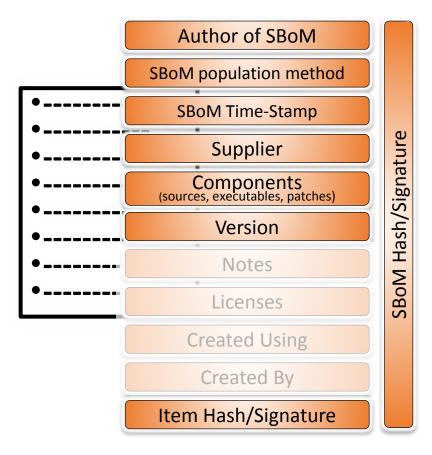


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SBoM elements

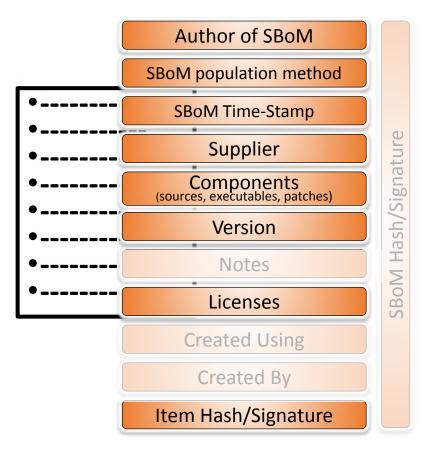


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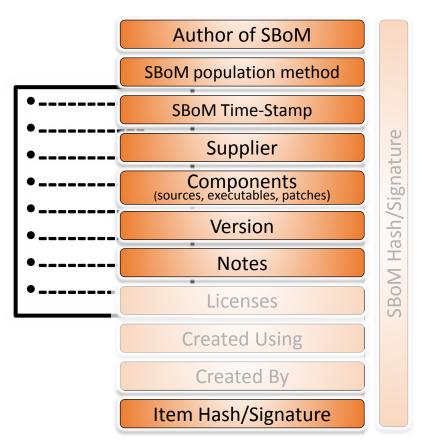


Correlated Info



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SBoM elements



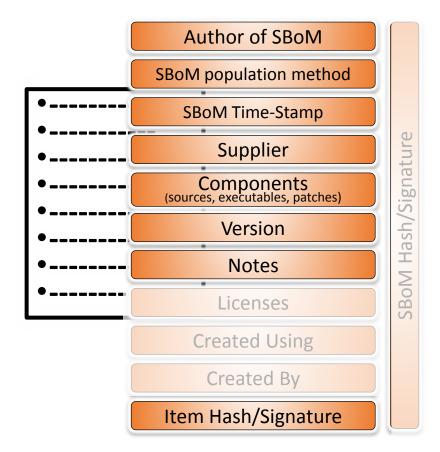
Correlated Info

Vulnerability Knowledge Bases
Vulnerability Management Systems



Refer, Transfer or Purchase (definition of what it is) Pedigree (history of how it was produced) Provenance (chain of custody of it) Integrity (cryptographic basis of unalteredness) **Intellectual Property** Constraints Known SW Vulns (known fixes are applied to it) Assurance (secure-safe-resilient) SBoM of a SW Service (SBoM of sw delivering service) Supply Chain Sequence Integrity

SBoM elements



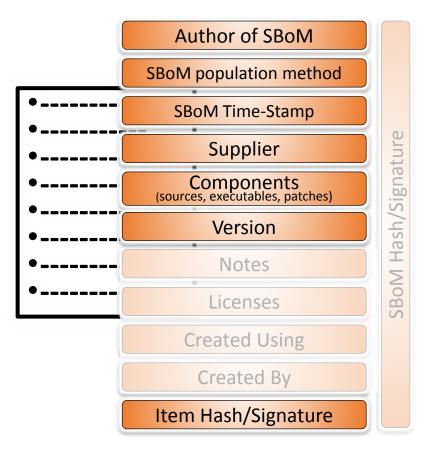
Correlated Info

Notes on exploitability of vulns
Vulnerability Knowledge Bases
Weakness Knowledge Bases
Assessment Results
Design Review
Code Review
Attack Surface Analysis
Static Analysis
Dynamic Analysis
Fuzz Testing
Pen Testing
Blue Teaming
Red Teaming
Organized as an Assurance Case



- Refer, Transfer or Purchase (definition of what it is)
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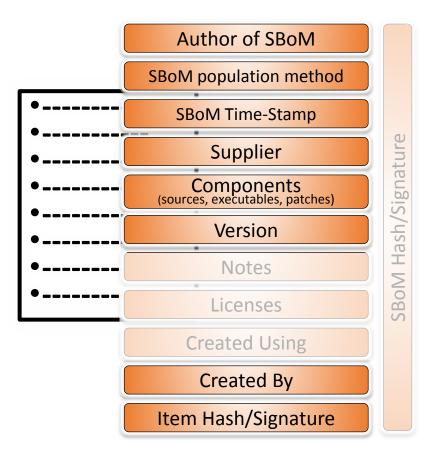
Correlated Info

Logging SBOMs of Services Used



- Refer, Transfer or Purchase (definition of what it is)
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- SBoM of a SW Service (SBoM of sw delivering service)
- Supply Chain Sequence Integrity

SBoM elements



Correlated Info

Desired sequence of ordered software supply chain steps, and requirements for each step for a specific project of interest

Launched 24 Sep 2019



STANDARDS -

USE CASES -

RESOURCES - A

ABOUT CISQ -

ACTIVE PROJECTS -

WORKING GROUP

HOME

TOOL-TO-TOOL SOFTWARE BILL OF MATERIALS EXCHANGE



DBUECTIVE

This is a joint working group of CISQ and the Object Management Group (OMG). Defining an exchangeable tool-to-tool software bill of materials (SBOM) metamodel is the primary good of this working group. The work inverages the efforts of the Netitional Telecommunications and Information Agency's pITIA(s) Software Compenent Transporency initiative but with a focus on the exchange of SBOMs between and among the software development tools that create, revise, manage, orchestrate, and/or otherwise manipulate software.

Like a bill of materials for physical items, the SBOM is a comprehensive inventory of the software raw materials, subassemblies, parts and components, needed to create a software product. Typically, an SBOM is hierarchical in nature and multi-level.

With today's software creation processes, many of these subassemblies will take the form of third-party components from open source software or other commercial

providers. Concerns about the origin and chain of custody can also be captured and conveyed with an SBOM, along with relevant information about the processivel and choices that the software creation activity underwent that can influence the customers' acceptance and confidence in the software's quality and appropriateness for the intended use by the customers.

TIMETABLE

The kick-off of this effort was 24 September 2019 with a three-day workshop on the concept and ideas for a tool-to-tool focused initiative.

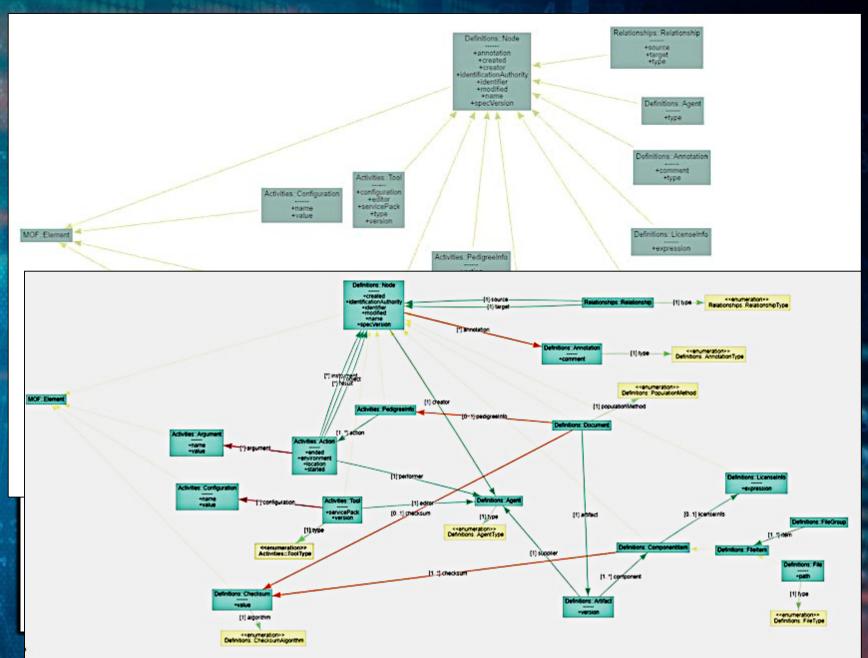
CHAIRS

- Bob Martin (M/TRE)
- Dr. Bill Curtis (CISQ)
- Kay Williams (Microsoft Azure CD Foundation)

PARTICIPANTS

- Philippe-Emmanuel Douziech (CAST)
- Sontiago Torres-Arias (in-tota/NYU)
- David Nolley (BlackBerry Apache Foundation)
- William Cox (Black Duck by Synopsys)
- Steve Lasker (Microsoft Artifact Storage, Open Container Initiative)
- Brian Russell (Google CD Foundation)
- Nitesh Bakliwal (Microsoft Windows)
- Kote Stewart (Linux Foundation SPDX)
- William Bartholomew (GitHub)
- David Edelsohn (IBM GCC)
- Jason Shaver (Microsoft Developer Division)
- Fahad Ahmad (Microsoft Build Systems)
- JC Herz (Ion Channel)
- Adom Baldwin (npm, Inc.)

- Gerald Heidenreich (Microsoft CloudBuild)
- Dan Lorenc (Google CD Foundation)
- Jeffrey Martin (White Source Software)
- Michael Muller (CAST)
- Bryan Sullivan (Microsoft Security and Compliance)
- Brian Fax (Sonatype)
- Steve Springett (OWASP, CycloneDX)
- Fred Blaise (CloudBees Jenkins)
- Ido Green (JFrog)
- Gary O'Neall (Source Auditor SPDX)
- Anna Debenham (Snyk)
- I an Geoghegan (Microsoft Software Supply Chain Security)
- Duncan Sporrell (sFractal Consulting)





Working with industry to Incorporate SBoMs into the Ecosystem of Software tools

Table 1: IDEs in Use Survey

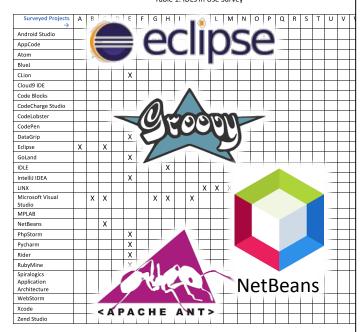


Table 2: Frameworks in Use Survey

Surveyed Projects →	Α	В	С	D	Ε	F	G	Н	1	J	K	L	М	N	0	Р	Q	R	S	Т	U	V	١
Bootstrap										Χ	Χ												
HTML5 Builder																							Ī
Microsoft Expression Studio																							
Visual Online																							Ξ



Working with industry to Incorporate SBoMs into the Ecosystem of Software tools

Table 3: Cloud Tools in Use Survey

Surveyed Projects →	Α	В	С	D	Ε	F	G	Н	1	J	K	L	M	N	0	Р	Q	R	S	Т	U	٧	ī
Azure							Χ			Х	Χ												ī
AWS CodeBuild												Χ		Χ									Ī
Cloud Foundry																	Χ						ī
Google Cloud Build							4	2															Ī
Kwatee						1																	Ī

ackage Repositories in Use Survey

					1																		
Surveyed Projects →	Α	В	ų,		E					J	K	L	М	N	0	Р	Q	R	S	Т	U	٧	T
Amazon ECR							1	-	-					Χ									t
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Beanstalk																					П		Γ
Bitbucket		Х	Х	Х						Х	Х	Х										•	Τ
Codebase								Х			Х			Х	1							,	Τ
Docker			Х	Χ	Χ				Χ		Х	Х	Х	Χ	,		v	7	1		,	-	Τ
GitHub			Х				Х	Х								7	-						Γ
GitLab			Х	Χ	Χ	Х			Χ						X		_	•					T
Glitch																(2i	+l	١,	uk	`		T
Google Container Registry																'	JI	LI	11	uı)		Ī
JFrog Artifactory				Χ																			ı
JFrog Xray				Х											`\	۸		j		•			T
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Phabricator					-										J			V	4				T
ProjectLocker															Ĭ								Ť
Repository Hosting										1				_									Ť
Savannah									м		ı		•	A	1		7		r	•	м		Ť
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Working with industry to Incorporate SBoMs into the Ecosystem of Software tools

Table 5: Build & Build Choreography Capabilities in Use Survey

Surveyed Projects →	Α	В	С	D	E	F	G	Н	T	J	K	L	М	N	0	Р	Q	R	S	T	U	٧	W	Х	Υ	Z
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Bamboo													- (3	4		ď.	7	V.								
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CruiseControl																· ^	C									
Final builder															U	ľ	·									
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Gitlab CI																Х					a		_	•		
GoCD																				- (7	1	'	7		
Integrity																				4	5		١,	3		
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TeamCity																			ı	1	7		4	10		
Terraform																			١	N	-	Y	V	7/	1	
Travis CI																			•	V	J		V	-	•	
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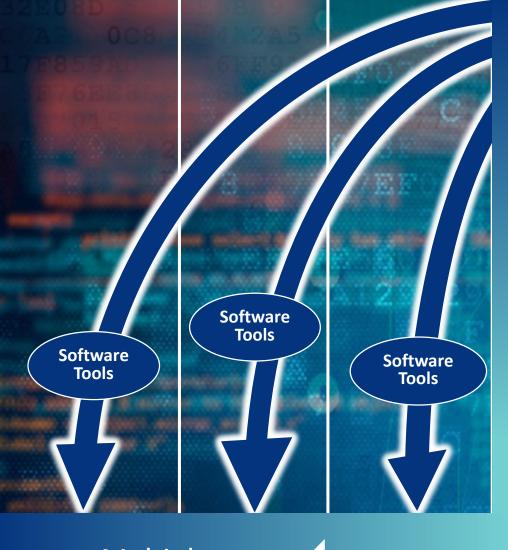
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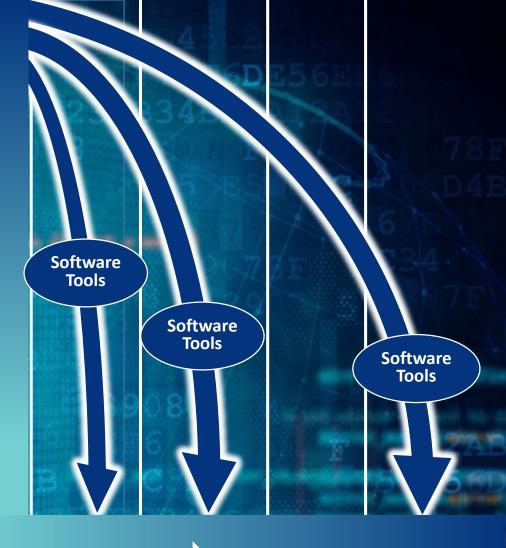
Whitepaper → CISQ → OMG RFC → ISO Std

- Socialize at Mar19 OMG meeting
- Draft SBoM as a Whitepaper in 3-day CISQ SBoM working session at Sep OMG meeting
- Prototype draft format in tool ecosystem, revise and draft RFC based on prototype results
- Co-submit draft RFC w/CISQ to OMG at Dec19 or Mar20 meeting
- iviar20/Jun20 OMG meeting charter FTF
- Jun20/Sep20 OMG meeting approve as OMG Standard
- Sep20/Dec20 Fast Track to ISO





Software Development, Integration, and Management Tools



Multiple Marketplaces



Software Bill of Materials (SBoM)

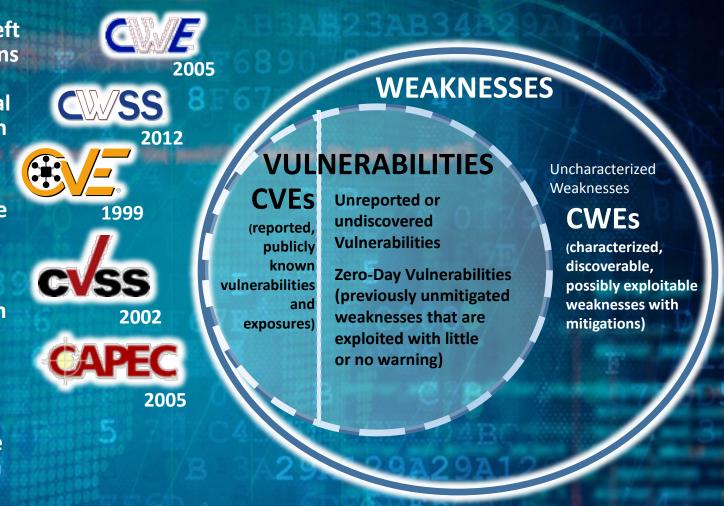
ENTERPRISE MEDICAL FINANCIAL SOFTWARE INDUSTRY RETAIL MINING

ENERGY MITRE

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Exploitable Weaknesses, Vulnerabilities & Exposures

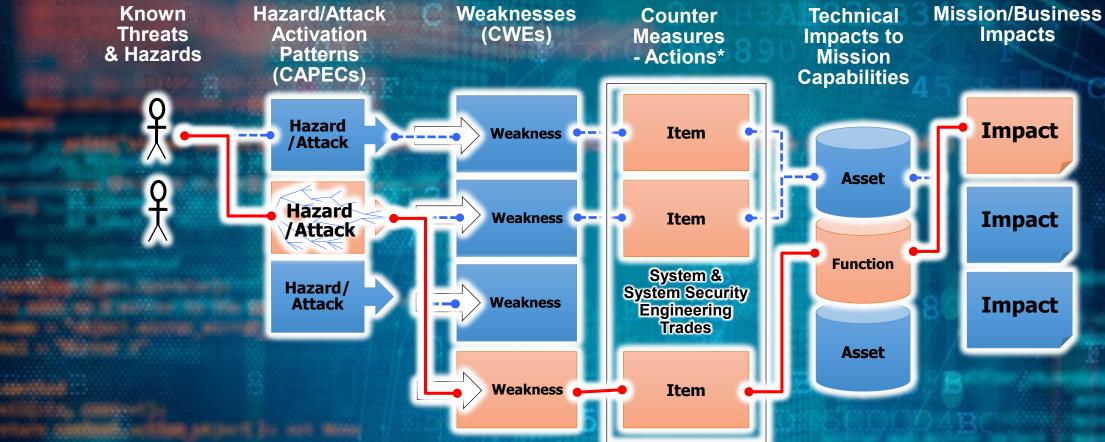
- Weakness: mistake or flaw condition in ICT architecture, design, code, or process that, if left unaddressed, could under the proper conditions contribute to a <u>cyber-enabled capability</u> being vulnerable to exploitation; represents potential source vectors for zero-day exploits -- Common Weakness Enumeration (CWE) https://cwe.mitre.org/
- Vulnerability: mistake in software that can be directly used by a hacker to gain access to a system or network; Exposure: configuration issue of a mistake in logic that allows unauthorized access or exploitation – Common Vulnerability and Exposure (CVE) https://cve.mitre.org/
- Exploit: take advantage of a weakness (or multiple weaknesses) to achieve a <u>negative</u> technical impact -- attack approaches from the set of known exploits are used in the Common Attack Pattern Enumeration and Classification (CAPEC) https://capec.mitre.org



The existence (even if only theoretical) of an exploit designed to take advantage of a <u>weakness</u> (or multiple weaknesses) and achieve a <u>negative technical impact</u> is what makes a weakness a <u>vulnerability</u>.



Assurance needs to address the Hazards & Attacks that can impact SW-Based Mission Functions



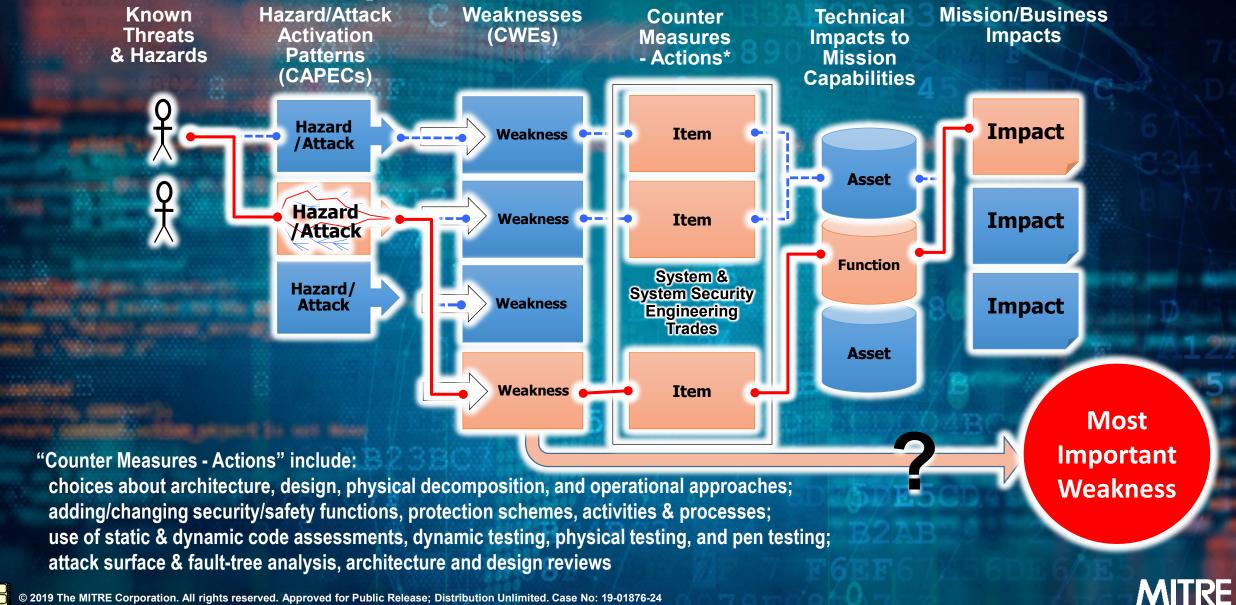
"Counter Measures - Actions" include:

choices about architecture, design, physical decomposition, and operational approaches; adding/changing security/safety functions, protection schemes, activities & processes; use of static & dynamic code assessments, dynamic testing, physical testing, and pen testing; attack surface & fault-tree analysis, architecture and design reviews





Assurance needs to address the Hazards & Attacks that can impact SW-Based Mission Functions





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

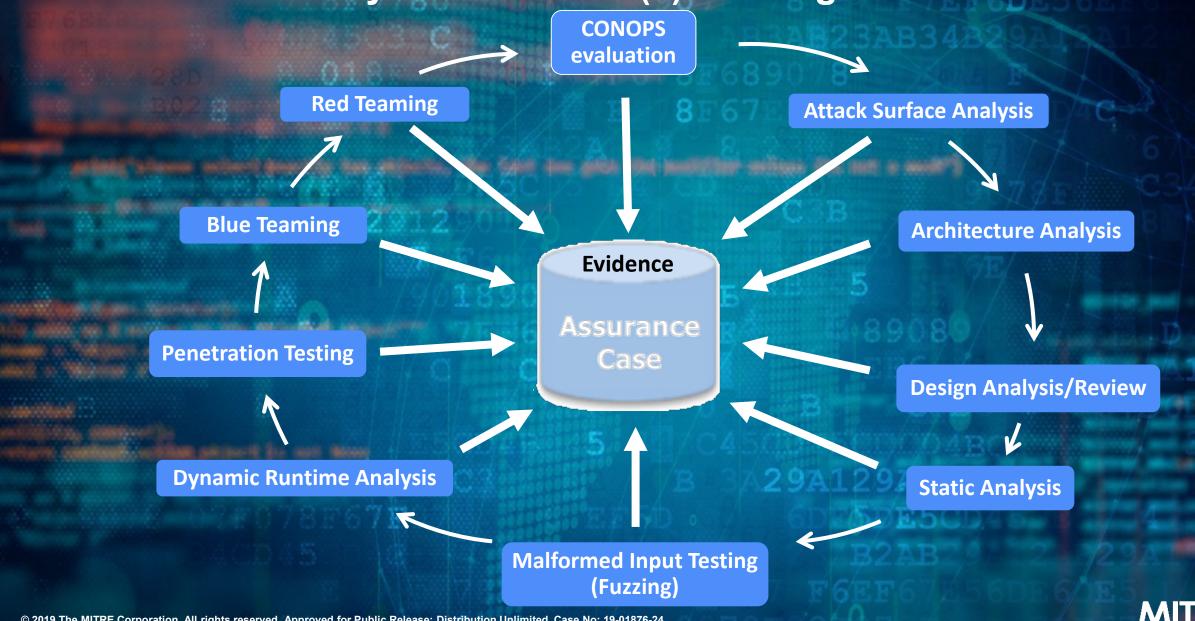
Artifacts Detection Methods Coverage **Design Review CONOPS Code Review Attack Surface Analysis** Requirements **Architecture Static Analysis Tool A** Design **Static Analysis Tool B Process** Code **Dynamic Analysis Tool C Binary Fuzz Testing Running Binary Pen Testing Environment of System Use of Mission Software Blue Teaming Red Teaming**



Most
Important
Quality
Issues



Multiple Sources of Assurance Evidence from Throughout the Lifecycle of the item(s) needing Assurance.



Different Perspectives on Assurance of Trust

Insurer

How do I underwrite?



What technology is needed to ensure trust?



Creator

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

Community

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





Acquirer

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

Operator

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



Commander/ Manager

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

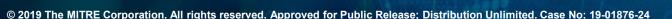


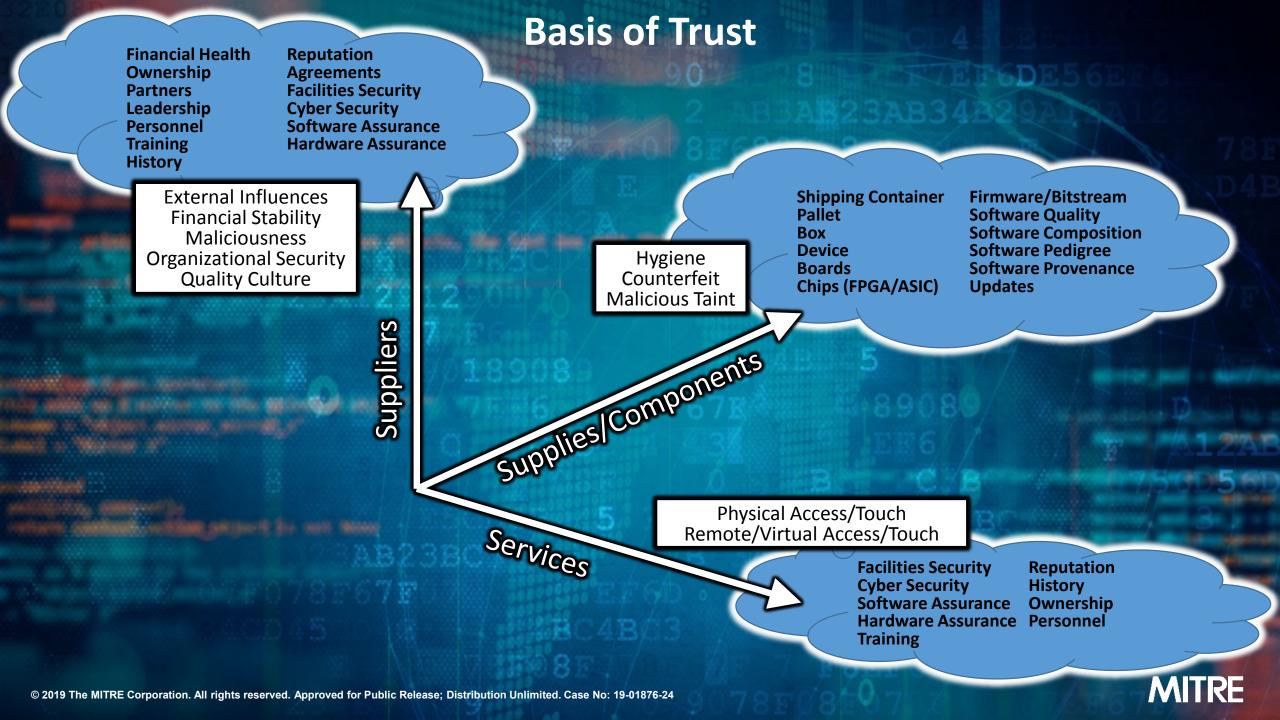


Patron

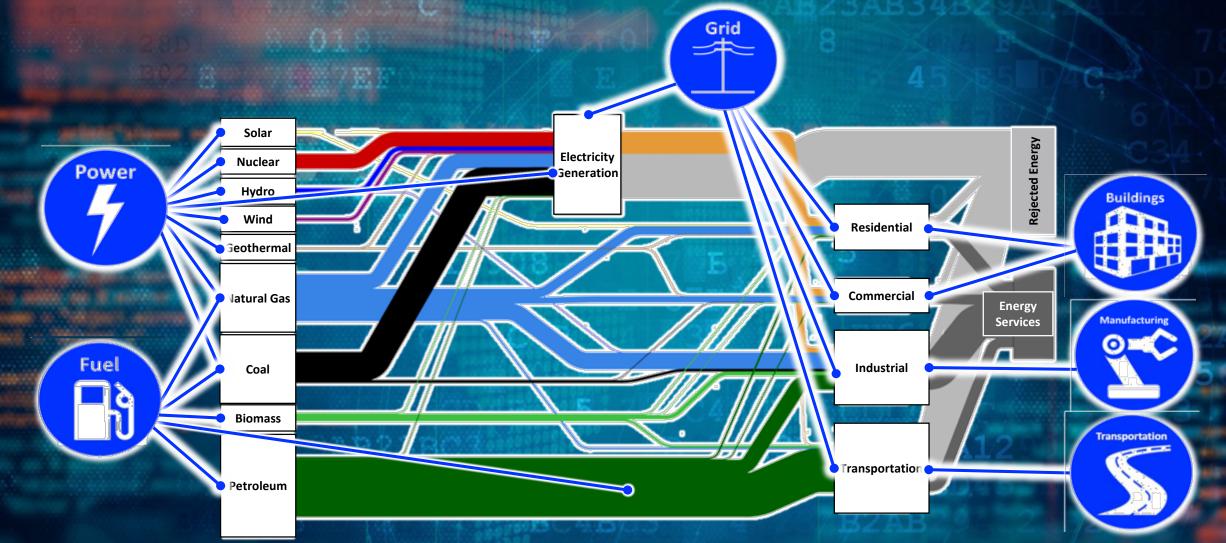
- Is it safe?
- Should I use it?
- Can I count on it?







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

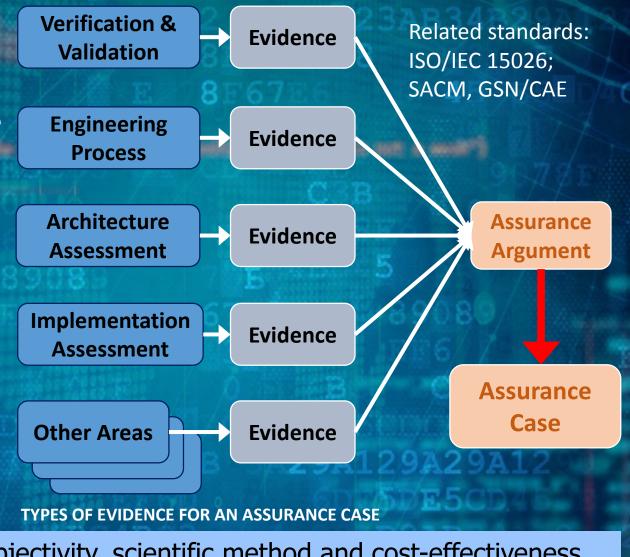


Establishing Assurance - Reducing Uncertainty

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



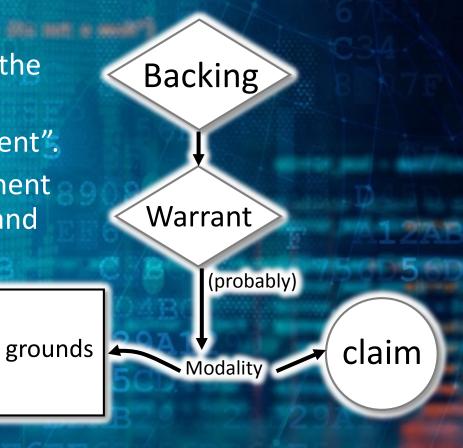
Confidence demands objectivity, scientific method and cost-effectiveness

Assurance 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



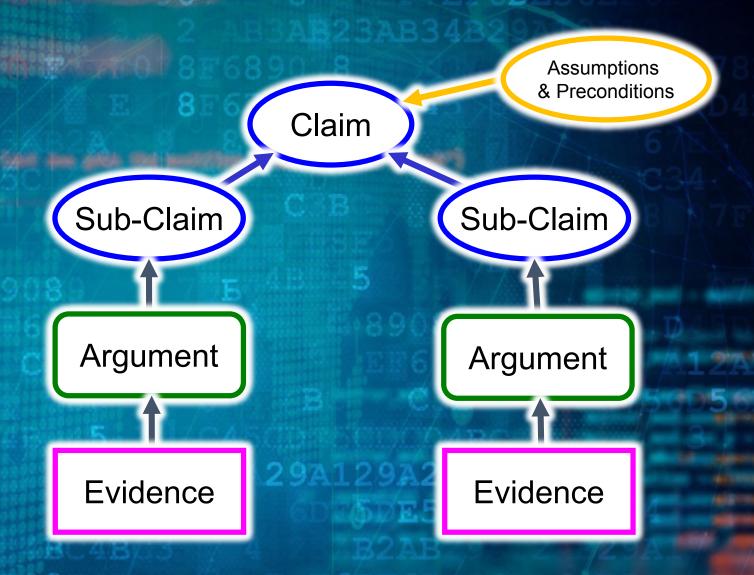


The Basics of an Assurance Case

Claim = assertion to be proven

Argument = how evidence supports claim

Evidence = required documentation





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 Pate: 5/31/2017

For questions regarding this document, please of Branch, Office of Device Evaluation at 301-790

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 fra

For questions pertaining to manufacturer report 301-796-6104 or via email at sharon kapsch@fi



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 510(k) 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 513(i) 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 and

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 ⁶

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.

⁵ Based on 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 S10(k). See 21 CFR 80.78 ((s)3). Note that a change to the intended us or tethonlogy of a 510(k). cleared foreign any render the device not substantially equivalent (NSE) to a legally marketed predicate. For detailed information about substantial equivalence and 510(k) submissions, refer to the FDA guidance entitled, The 510(k) Program: Evaluating Substantial Equivalence in Premarked Notifications (510(k)).

(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. Dure. and Cosmetic Act.

Support for Safety Case Generation via Model Transformation

Chung-Ling Lin, Wuwei Shen Department of Computer Science Western Michigan University Katamazoo, MI, USA (chung-ling lin, wuwei shen)@wmich edu Richard Hawkins
Department of Computer Science
The University of York
York, UK
richard hawkins@york ac.uk



ABSTRACT
Assessing the safe soyloans under ever confidence is a grain. The safe soyloans under the use of assurance lidet or too method the use of assurance lidet or too much all affect confidence of automatic generate expedite a developp perform compliance framework which mechanoded, and a generate a safety a conformance of the use the GPCA in feet this framework can pump guidance pub

Keywords Compliance chec systems; safety cas

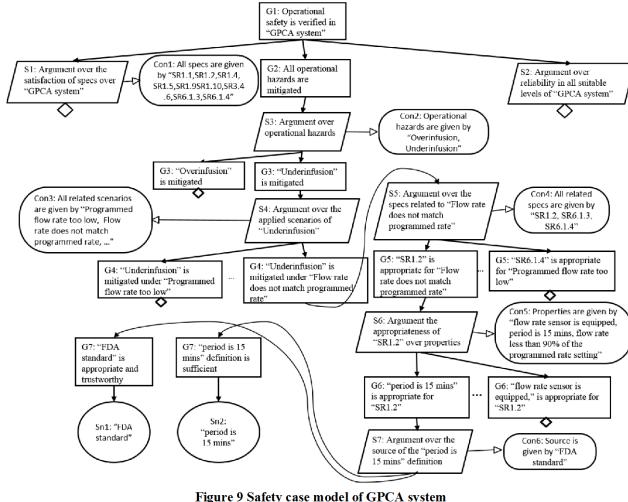
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constraints with an challenge for indust to address this is a safety case in short Administration (FI guidance document pumps [2], which a use safety assummer organize and puses chains of their infusion pump guantomatically constructions on the safety and puses chains of their infusion pump guantomatically constructions.

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⁶ For more information about assurance case reports, see, for example: Graydon, P., J. Knight, and E. Strunk, "Assurance Base Development of Critical Systems," Proc. of 37th Annual International Conference on Dependable Systems and Networks, Edinburgh, U.K., 2007; Kelly, T., Arguing Safety — A Systematic Approach to Managing Agiety Cares, Ph.D. Dissertation, University of York, U.K., 1998; Kelly, T., "Reviewing Assurance Arguments, A Siep-by-Step Approach," Proc. of Workshop on Assurance Cases for Security — The Metrics Challenge, Dependable Systems and Networks, July 2007; Kelly Tim, and J. McDermid, "Safety Case Patterns – Resening Successful Arguments," Proc. of IEE Colloquium on Understanding Patterns and Their Application to System Engineering, London, Apr. 1998; Weinstock, Charles B. and Goodnongly, John B., "Yowards an Assurance Case Practice for Medical Devices," Camegie Mellon Software Engineering Institute, October 2009; Hawkim, Richard, et. al., A New Approach to Texting Clear Safety Arguments, Safety-critical Systems Symposium, Southampton, U.K. Februs, 2011; UK Ministry of Defence, Defence Standard 00-56, Safety Management Requirements for Defence Systems — Part I and Part 2 June 2007.



The Assurance Case











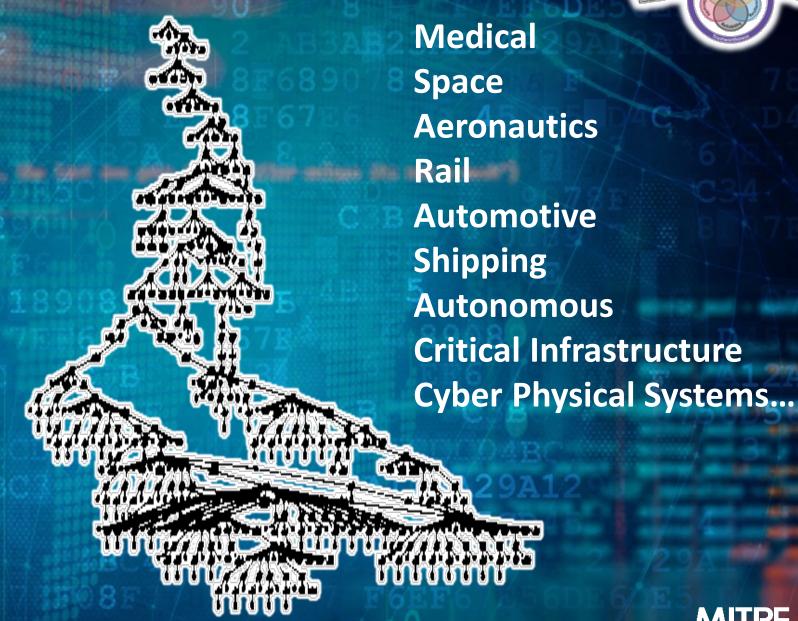




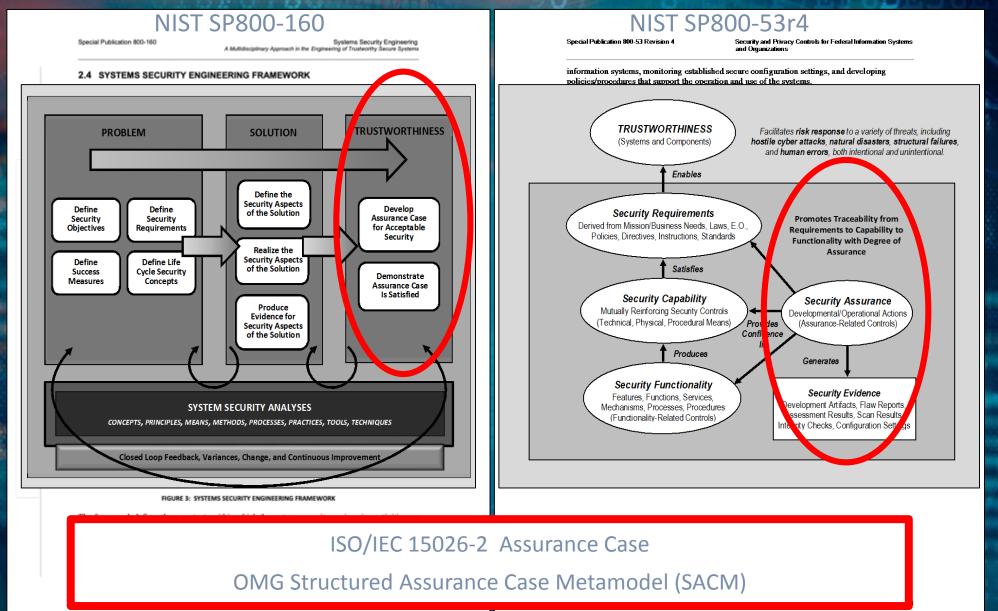




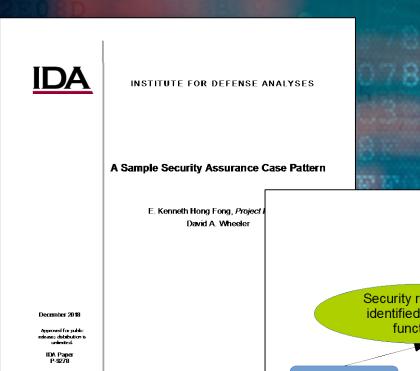
Dependability Engineering Innovation for Cyber Physical **Systems**



Communicating Assurance to Gain Trust

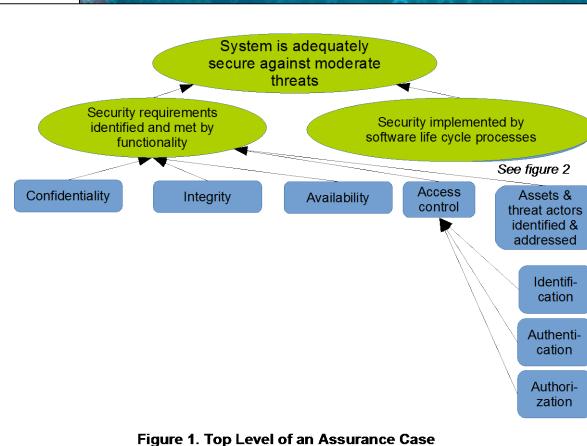




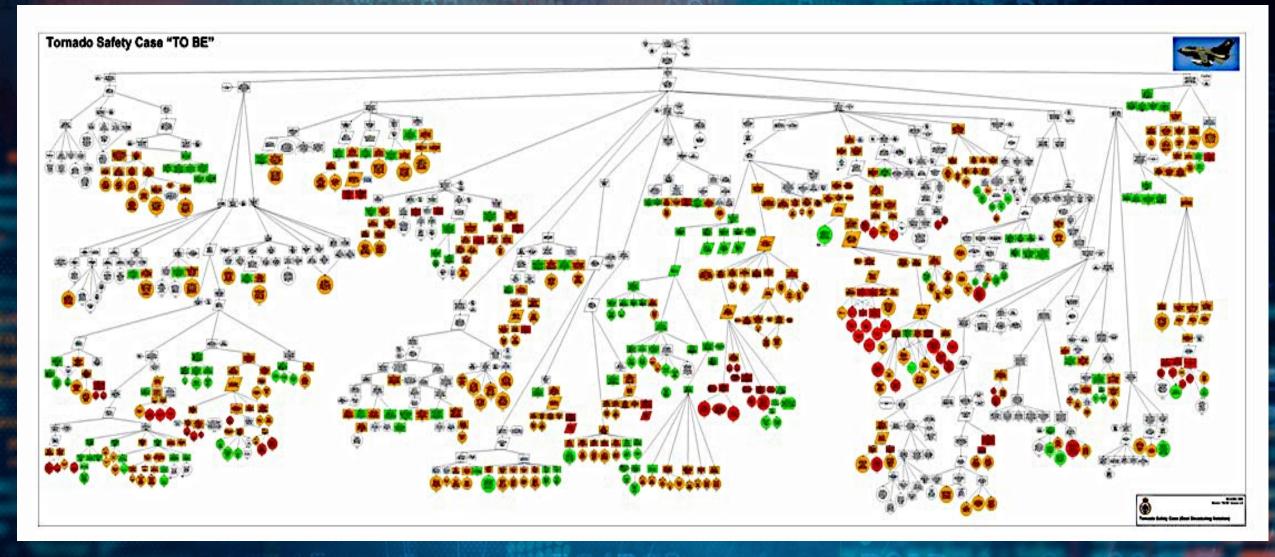


Contents

ш	noducion	I
Sa	mple Assurance Case Pattern	2-
A.	Top Level	2-
В.	Life Cycle Processes	2-
	1. Security in Design	2-
	2. Security in Integration and Verification	
	3. Security in Transition and Operation	2-
	4. Security in Maintenance	2-1
	5. Certifications and Controls	2-1
C.	Implementation	2-1
	1. Common Implementation Errors Countered	2-1
	2. Common Misconfigurations Countered	
	3. Hardening Applied	
	Securely Reuse Software	2-1
D.	Other Life Cycle Processes	2-1
E.	Real Assurance Cases Include Supporting Text	2-1
F.	Determining Adequacy	2-1
Sa	mple Assurance Case Application	3-
A.	Top Level	3-
	Sample Supporting Text: Email Addresses	3-
	2. Sample Supporting Text: Data Modification Requires Authorization	
	3. Sample Graphical Representation That Data Modification Requires	
	Authorization	3-
В.	Life Cycle Processes	3-
C.	Implementation	3-
D.	Other Life Cycle Processes	3-1
Cc	onclusions	4
	ix A . Processes Are Neither Phases nor Stages	
	ix B. How an Assurance Case can Support Other Documents and Process	
1.	DoD Instruction 5000.02	
2.	DoD Program Protection Plan (PPP)	
3.	DoD Cybersecurity Strategy	
3. 4	DoD Instruction 5200.44	
	NIST Cybersecurity Risk Management Framework (RMF) / DoDI 8510	
5.	, , , , , ,	
6.	NIST SP 800-160 volume 1	
7.	ISO/IEC/IFEE 12207	В



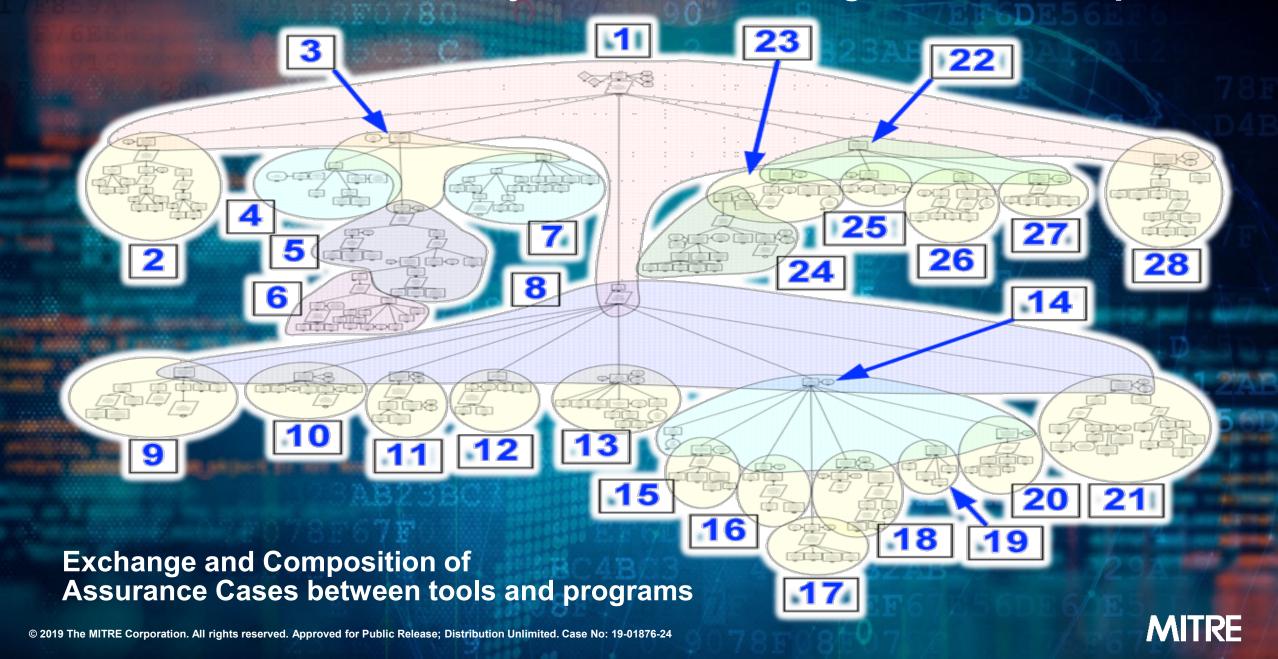
Tornado Operational Safety Case



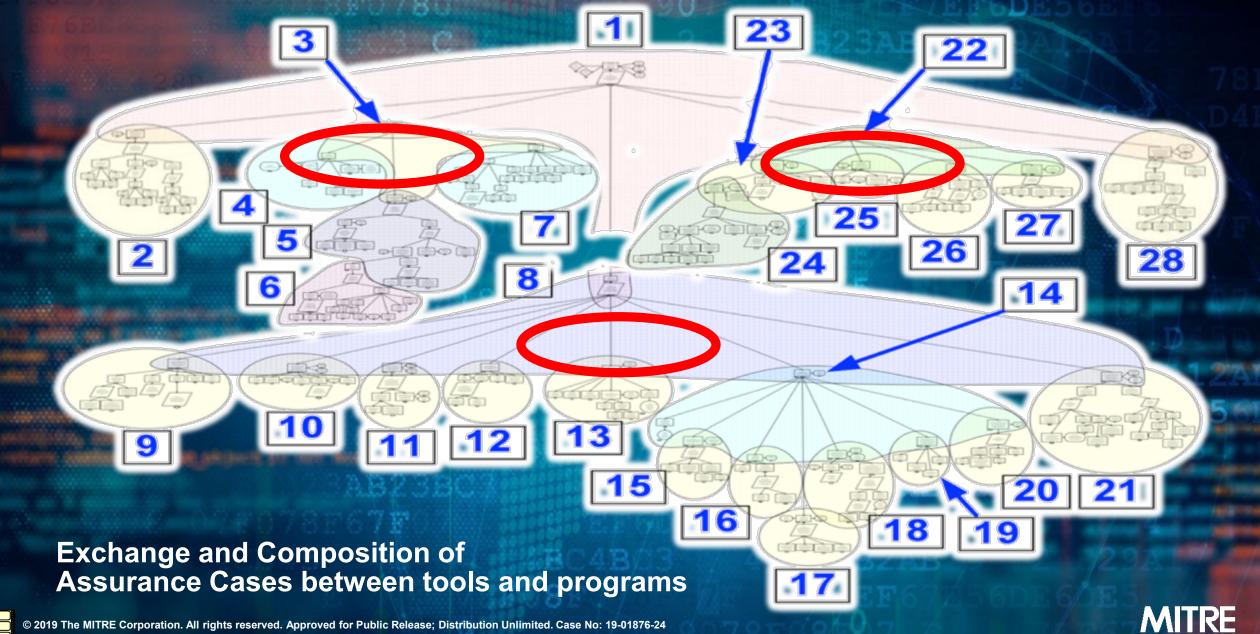
Apportionment of Ownership:
White = Generic, Green = Air Command, Orange = DE&S, Red = Contractors



The Assurance Case for a System Builder using Assured Components



The Assurance Case for a System Builder using Assured Components



TRANSPARENT ASSURANCE AS A BASIS FOR TRUST - FUTURE **Services** Software SaaS **Hardware SOFTWARE INTEGRATOR OEM SOLUTION PaaS PROVIDER ODM** Assurance **Development** Tools Case Software Modules laaS Stack FRAMEWORK •• CONTAINER O o guest os Chips HYPERWSOR O o F&RMWARE Trust MITRE

Questions?

IIC Journal of Innovation – September 2018 issue on Trustworthiness https://www.iiconsortium.org/journal-of-innovation.htm

"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





