Intrinsically Secure, Open, and Safe Cyber-physically Enabled, Life-critical Essential Services (ISOSCELES)

AADL Committee Meeting
2017-06-07
Todd Carpenter, Chief Engineer, Adventium Labs
Dr. John Hatcliff, Kansas State University
Dr. Kevin Fu, University of Michigan

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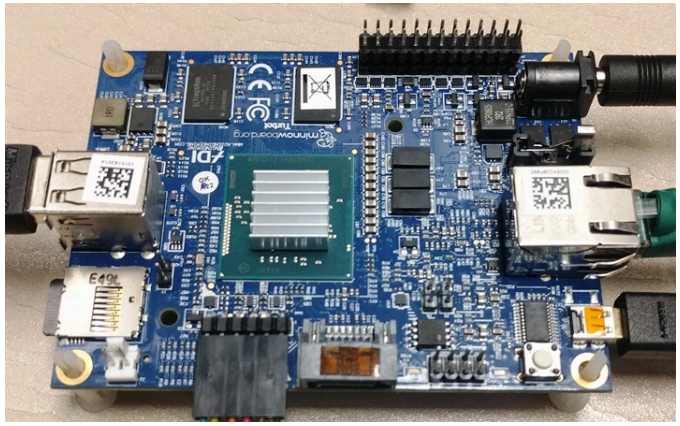
Executive Summary

Need:

- Inadequate security of many networked medical devices can lead to *unacceptable risk* to patients, clinics, and businesses.
- The lack of evidence of good security designs will delay FDA approval.

Approach:

- We are developing a partitioned safe and secure medical device platform.
- Medical device companies can build their medical application on this platform.
- ISOSCELES will produce open-source *education*, *requirements*, *model-based designs*, and *example HW & SW implementations*.



Benefits:

- Shorter time-to-market for safe and secure devices.
- Fewer security issues with fielded devices.
- Easier updates when patches are necessary.

Competition:

- Attempt to apply IT security to medical devices.
- Pay someone else to do it, with no way of determining quality of results.
- Rely on testing, check-lists, and compliance-based approaches.

ISOSCELES will spur safe and secure innovation.

ISOSCELES Team

US Department of Homeland Security Project, CPS Security Program, $2.2million for 3 years

Adventium Labs

- Todd Carpenter (PI) – Safety and security critical systems including avionics, industrial control, medical devices, and weapons systems.
- Dr. Steve Harp – safety and security critical systems, architecture design.
- Jim Carciofini – safety critical system design and engineering, model based systems engineering.
- Steve Johnston – embedded systems development.
- John Gohde – software engineering, security.

Kansas State University:

Information and Telecommunications Technology Center

- Dr. John Hatcliff (PI) – Safety critical model-based medical device design.
- Dr. Eugene Vasserman – Medical device security.
- Brian Larson – PCA pump, model based systems engineering.

University of Michigan:

Security and Privacy Research Group

- Dr. Kevin Fu – Medical device security evaluation.

Medical Device Industry Needs

80% of device manufacturers have 50 or fewer employees.

https://www.selectusa.gov/medical-technology-industry-united-states

- Companies focus on therapy and diagnostic innovations.
- Start-ups rarely have the resources to build in security from scratch.

Small companies need tools and templates.

Large device manufacturers have demonstrated poor security implementations with their fielded devices.

- Devices depend on old, unpatched operating systems and libraries.
- FDA Safety Alerts have been issued for vulnerable networked devices.

Large companies need appropriate security solutions.

Developer Needs

- Expert embedded systems security developers are rare and expensive.
- IT security experts often lack experience with:
  - Constrained embedded systems.
  - Safety, integrity, and availability.
  - Quality systems, including formal requirements and design.
- MedCo quality systems focus on safety.
  - Not set up for business risks.
  - Difficult for developers to motivate non-safety related security.

Most Top Computer Science Programs Skip Cybersecurity

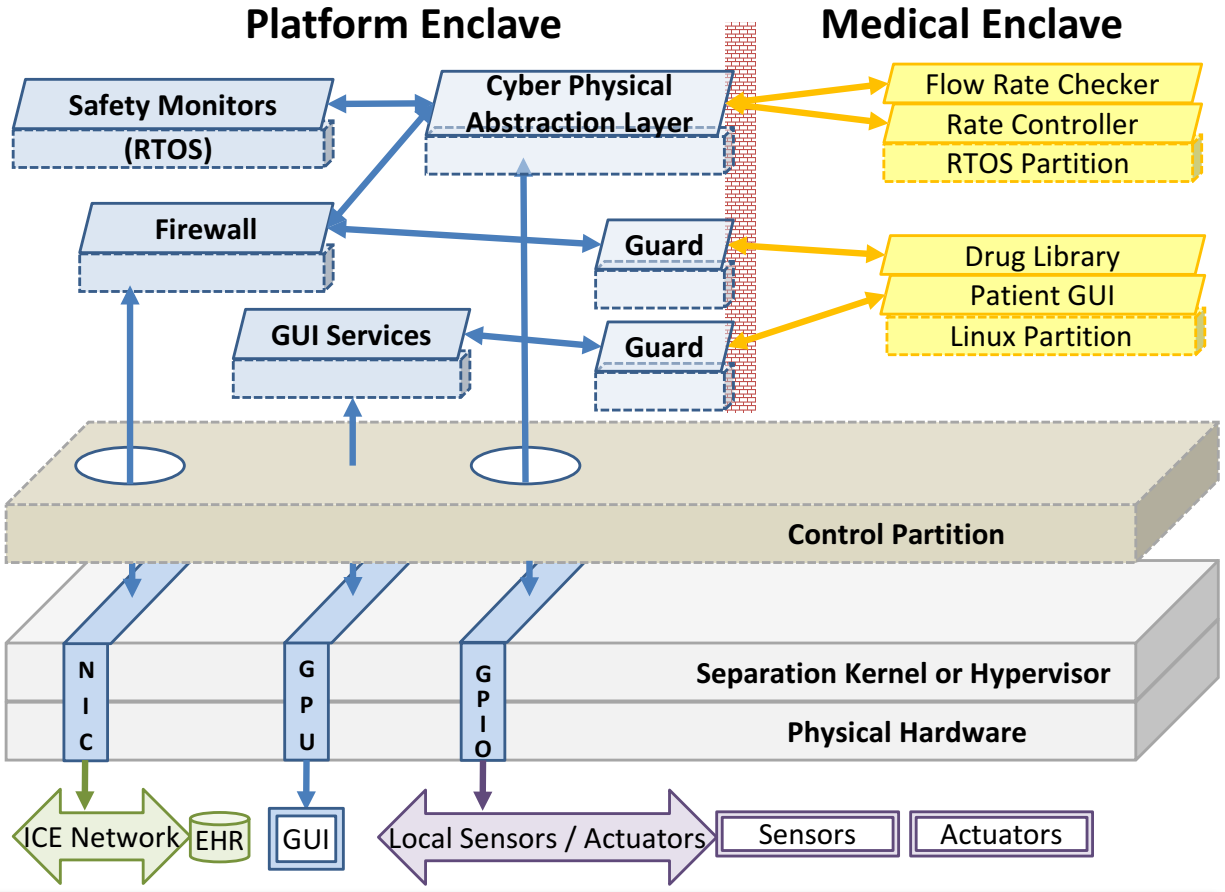
- Only three of the top 50 university computer science programs in the United States require students to take a cybersecurity course.
- Many don't even offer a class on the subject.
- Graduates of computer science and engineering programs are not qualified to fill cybersecurity positions.
- 200,000 US cybersecurity job openings are unfilled

http://theinstitute.ieee.org/career-and-education/education/most-top-computer-science-programs-skip-cybersecurity

Developers need a foundation to build upon.

ISOSCELES Model Driven Separation Approach

- Model-driven, configurable medical device platform.
- Separate networking, safety, and security functions from the medical application.
- Auto-generate device internal communications and processing directly from the models.



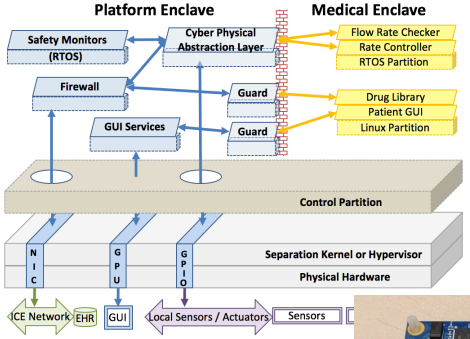
Architecture separates networking from safety functions.

ISOSCELES Product-Line Engineering Approach

ISOSCELES-based Medical Devices

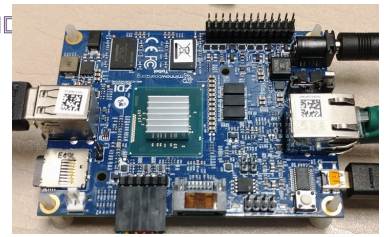
(note: concept illustrated – pictured devices not built using ISOSCELES)

ISOSCELES platform assets are instantiated/configured to develop devices for specific care-giving functions



Hypervisors / Micro-kernels

- Zen
- SeL4
- …

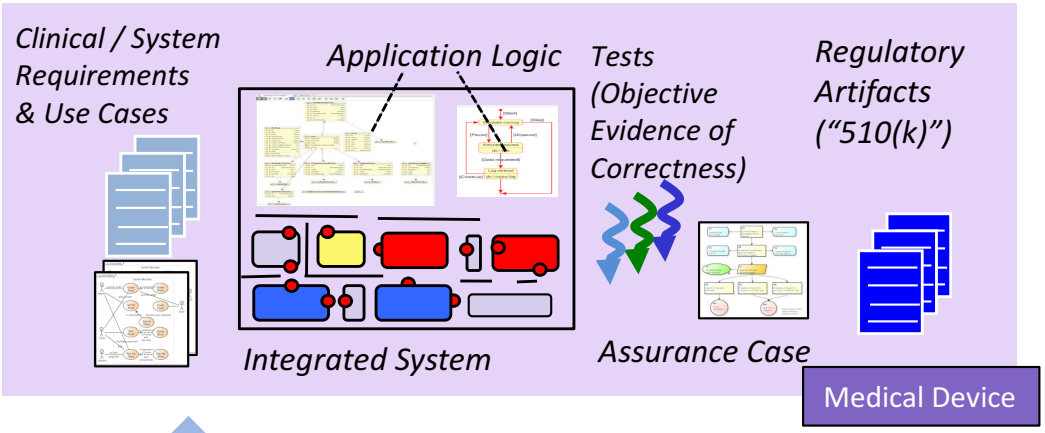


Safety/Security Services

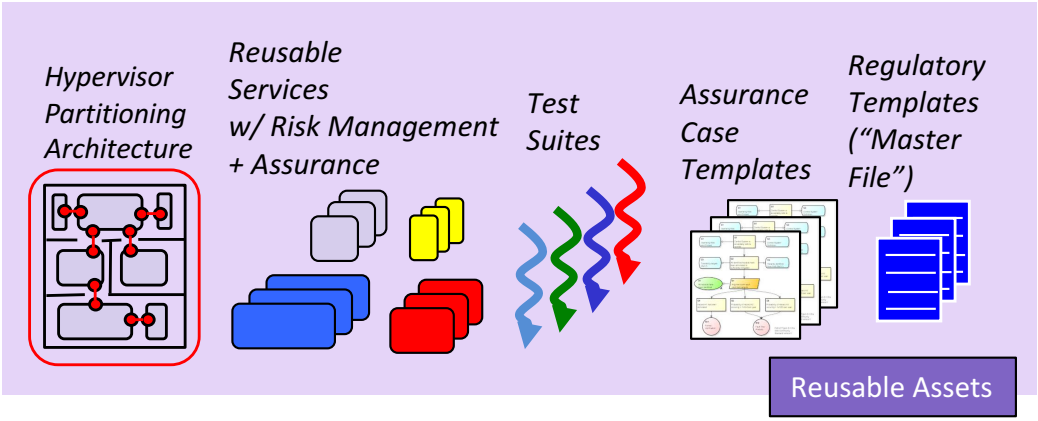
- Process Partitioning
- Communication Partition
- Encryption
- Authentication
- Logging
- Etc.

ISOSCELES Platform Assets

Application Engineering



Systems Engineering process for instantiating platform assets

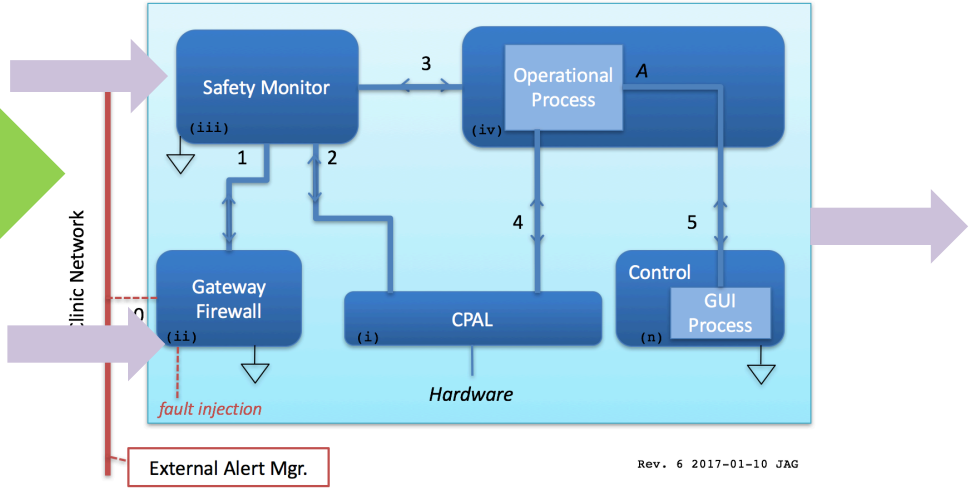


Domain/Platform Engineering

From Spaghetti to Partitioned Architecture

Typical Embedded Device

Strongly Partitioned Function/Communication



Use of ISOSCELES model-driven hypervisor technology to achieve strong partitioning in runtime architecture

Benefits to Stakeholders

- Separate networking, safety, and security functions from the medical application
- Fault isolation
- Easier / better handling of updates (updating only relevant partitions) and reassurance
- Etc.

Patient-Controlled Analgesic (PCA) Pump

PCA Pump Background

- PCA Pump is used to pump an analgesic drug (opioids, pain-killers) into a patient's intravenous infusion (IV) line to provide pain relief
- The infusion is "patient controlled" because the patient presses a button to release a dose of the drug. The "burst of drug" released when the button is pressed is called a "bolus dose"

PCA Pump on ISOSCELES

- FDA created "Infusion Pump Improvement Initiative" due to safety concerns for pumps.
  https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202501.htm
- ISOSCELES will develop a prototype infusion pump using the ISOSCELES platform
- PCA Pump device selected because
  - KSU previously developed extensive pump artifacts w/ FDA engineers in **NSF FDA Scholar-in-Residence Program**
  - PCA example is widely used in current standards development for interoperable systems

ISOSCELES Development – Primary Elements

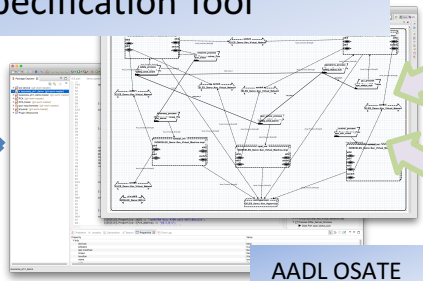
Medical Device Requirements

Risk Management (Safety, Security Analysis)

Assurance Cases V & V Evidence

Regulatory Artifacts

ISOSCELES Architecture Specification Tool



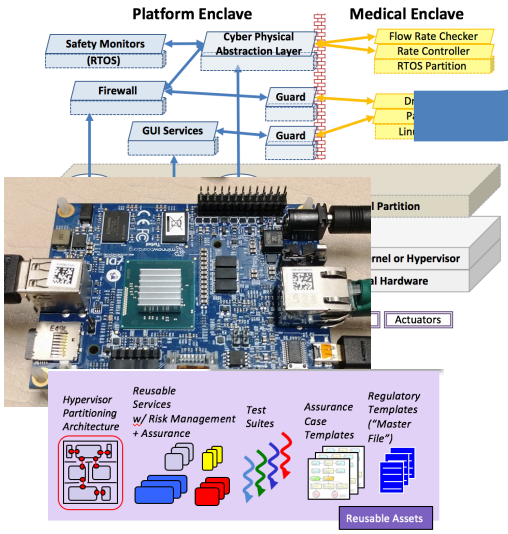
AADL OSATE

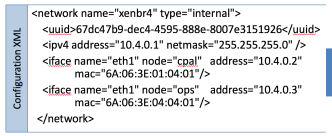
Medical Device Software

Medical Device-specific Hardware (sensors, actuators)

ISOSCELES platform configuration and device development is organized in a **model-centric** development process.

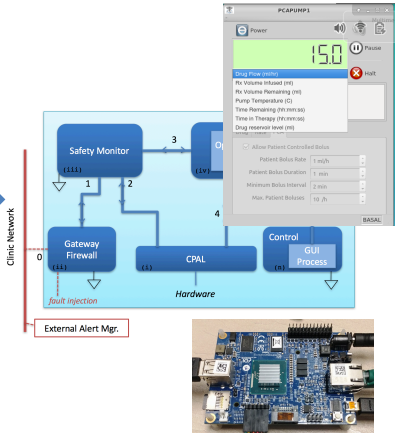
ISOSCELES Platform Assets





ISOSCELES Platform Configuration (XML)

ISOSCELES Platform Deployment & Configuration Framework

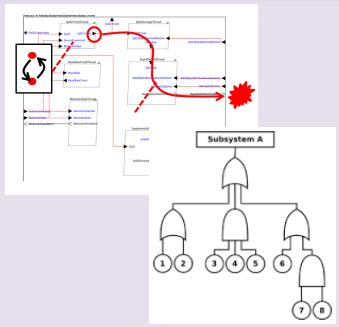


ISOSCELES Platform Run-Time Environment

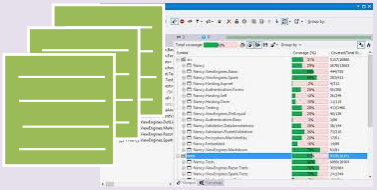
ISOSCELES Stakeholder Artifacts

ISOSCELES focuses not only on software/hardware, but also addresses **artifacts** necessary to help manufacturers integrate ISOSCELES into their development context, align with relevant standards, and support regulatory submissions.

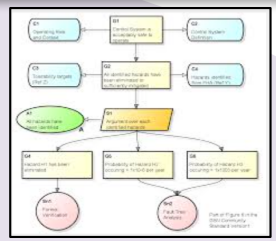
Risk Management (Safety/Security Hazard Analysis)



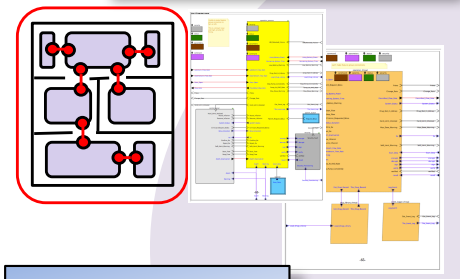
V & V artifacts (test suites/ reports)



Assurance Cases



Architecture Models (design)



Standards Compliance

Underwriters Laboratories

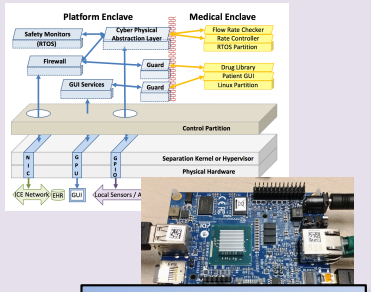
AAMI
Advancing Safety in Healthcare Technology

ISO IEC

Requirements

Regulatory Submission Artifacts

US Food & Drug Administration
FDA
APPROVED

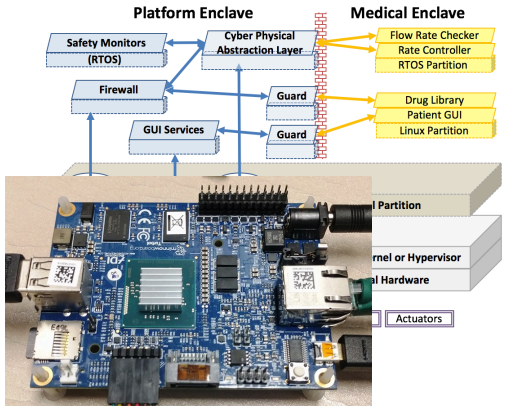


Hardware & Software

Constellation of artifacts necessary for using software/hardware assets in regulated industry context

Modeling Platform Assets [Demo OSATE]

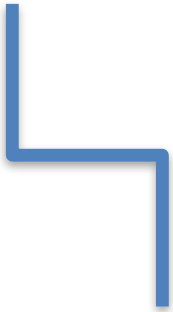
ISOSCELES Platform Assets



Hypervisor Building Blocks

Partitions / Virtual Machines

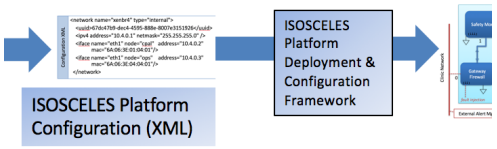
Virtual Networks



Hypervisor Building Blocks Properties

- General
  - UUID, etc.
- VM
  - OS
  - Memory
- Networking
  - IP Address
  - IP Network Mask
  - MAC Address
- Logical Communication
  - Protocols
  - QoS

Reminder: Tool Chain Pipeline



When the ISOSCELES deployment and configuration framework encounters instances of these modeling building blocks in the XML-based configuration info, it will do the appropriate instantiation/implementation in the "build" of the platform instance.

ISOSCELES Safety/Security Services

- Firewall
- Network Guards
- Authentication
- Encryption
- Logging
- …

Medical Device Domain Building Blocks

- Medical Domain Information Schema
- Physiological Data Representations
- GUI Services
- Sensor/Actuator Driver wrappers
- …

Model-based Systems Engineering (MBSE)

- Capture separation design in AADL.
- Analyze the models to provide evidence, e.g., of separation, performance.
- This reduces test burden.
- ISOSCELES will then automatically configure the platform:
  - Partition configuration.
  - Network connectivity, separation, firewall rules.
  - Safety monitors.
  - Module APIs.

AADL

```
connections
  cpal_status_1: port cpal_server_process.cpal_status_pub ->
                 operations_process.cpal_status_sub {
    Actual_Connection_Binding => (reference (xenbr4));  };
  cpal_status_2: port cpal_server_process.cpal_status_pub ->
                 safety_process.cpal_status_sub {
    Actual_Connection_Binding => (reference (xenbr2));  };
```

Configuration XML

```
<pubsub_channel name="cpal_status">
  <port name="CPAL_PUBPORT" protocol="TCP">5001</port>
   <publisher node="cpal" process="cpal-server" address="*"/>
   <subscriber node="ops" process="operations"
address="10.4.0.3"/>
   <subscriber node="safety" process="safety"
address="10.2.0.7"/>  </pubsub_channel>
```

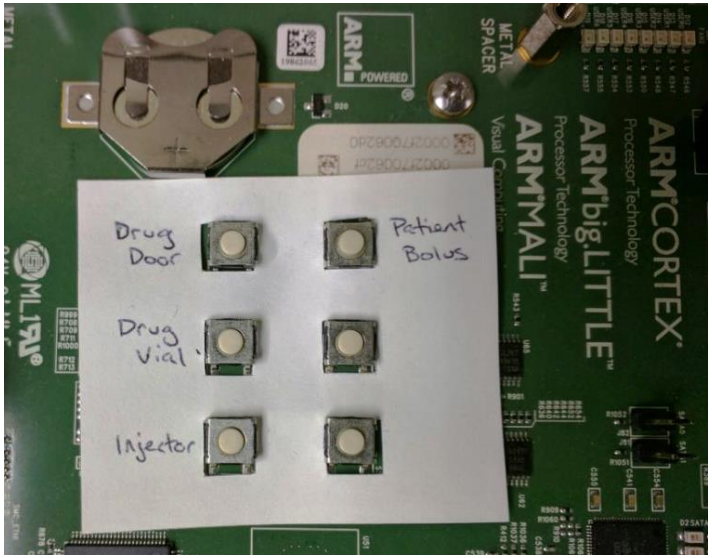
AADL models will drive system configuration.

Separation Layer

- Open source Xen hypervisor provides separation in initial prototype.
- Software demonstration runs on AMD G-series SoC, Intel Atom prototyping boards, and PCs.
- We will select and mature one separation approach in 2017.
  - Balance provable separation, cost, and features.
  - Mature embedded systems support is an issue.
- We want platform flexibility; one size does not fit all.
- We will extract information from AADL into an intermediate form that we can target to different separation layers.

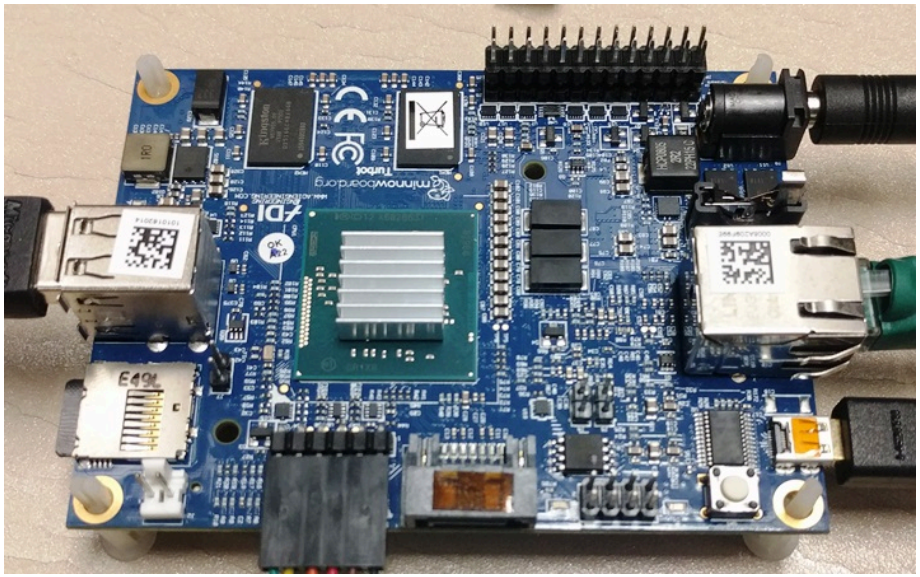
Current focus is on the Xen hypervisor and SeL4.

Prototype Hardware



Current boards:

- ARM v7 Arndale, Tegra TK1 (seL4)
- ARM v8 Juno (Linux)
- AMD x64 iEi G-series (Xen)
- Intel ATOM Minnowboard (Xen)



Multiple targets and environments will reduce adoption costs.

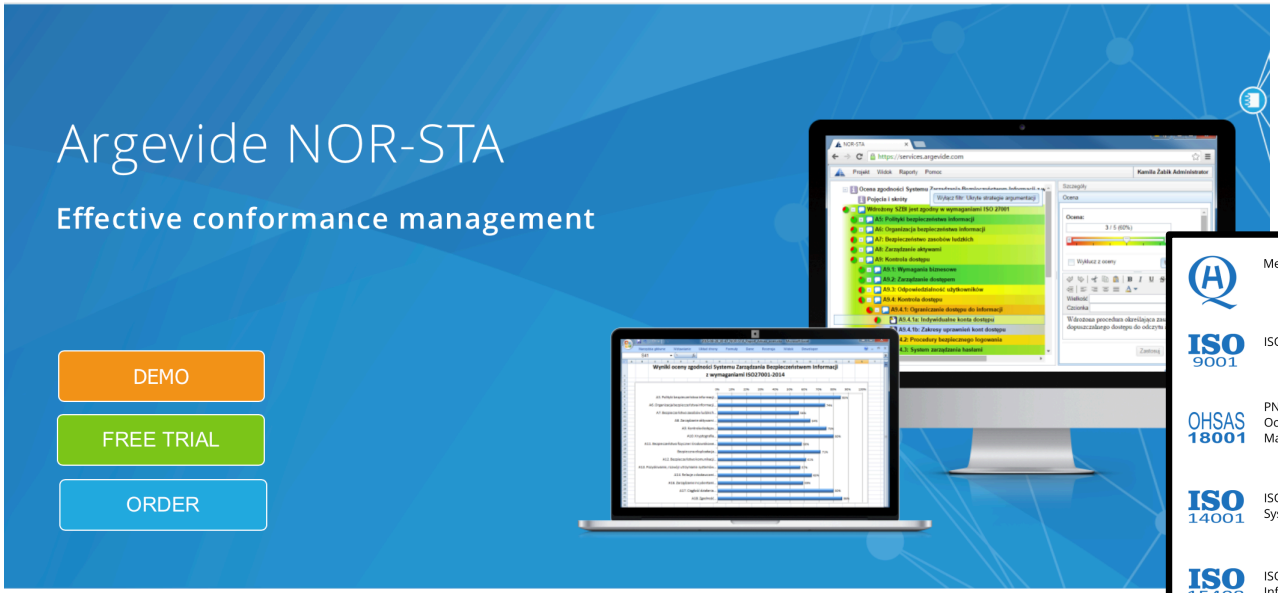
Conclusions

- Demo Goals:
  - Illustrate our initial use of hypervisor technology (from point of view of both platform manufacturer and device manufacturer)
  - Illustrate model-based development methodology and workflow
- Next Steps
  - Further vetting demo concept with device industry partners and FDA collaborators
  - Investigating additional hypervisors/micro-kernels in the context of end-to-end development
  - Adding realism and greater configurability to both the platform and PCA device elements

EXTRA SLIDES

Industrial Integration – Assurance Artifacts

Argevide produces the **NOR-STA assurance case tool** used in a number of safety-critical domains by industrial clients throughout Europe.



Standards targeted by NOR-STA with built-in support.

	Medical Standards	ISO 27001	ISO 27001 Information Security Management
ISO 9001	ISO 9001 Quality management systems	IEC 62443	IEC 62443 Security for industrial automation and control systems
OHSAS 18001	PN-N 18001 / OHSAS 18001 / ISO 18001 Occupational Health and Safety Management	ISO 26262	ISO 26262 Road vehicles – Functional safety
ISO 14001	ISO 14001 Environmental Management Systems	IEC 61511	EN/IEC 61511: Functional safety – Safety instrumented systems for the process industry sector
ISO 15408	ISO/IEC 15408 Common Criteria for Information Security Evaluation	ISO 17065	ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services
HACCP	HACCP Hazard Analysis and Critical Control Points	caf	Common Assessment Framework CAF 2006 and CAF 2013

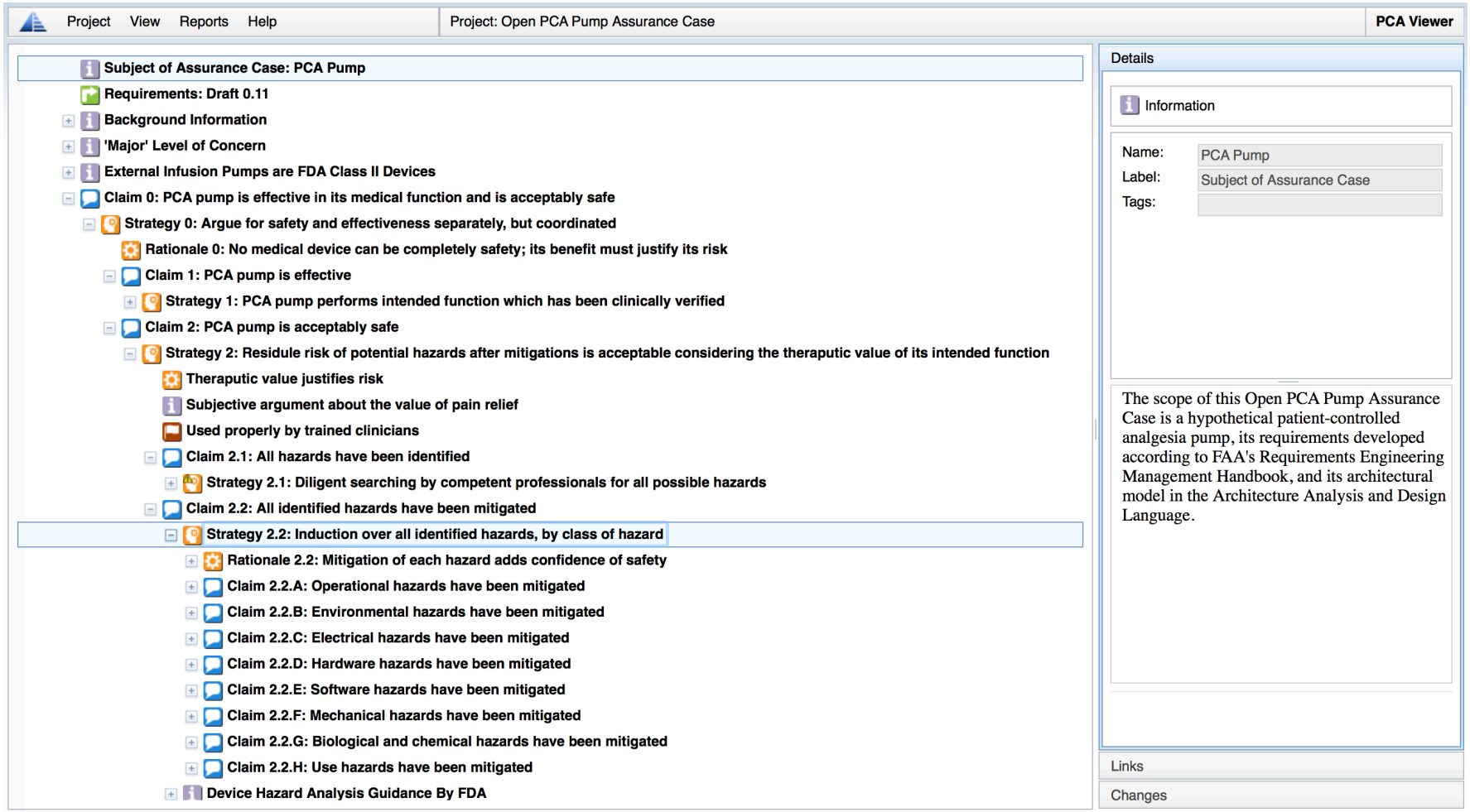
- KSU worked with Argevide to get FDA funding to develop an assurance case template to be used in regulatory submissions to FDA.
- Now working with Argevide and FDA to develop templates and examples for safety/security assurance cases for interoperable medical devices – aligned with assurance structures used in AAMI/UL 2800

https://www.argevide.com

Industrial Integration – Assurance Artifacts

Preliminary version of ISOSCELES PCA Pump Assurance Case in NOR-STA tools

(DEMO: walk-through NOR-STA web-interface for pump assurance case)



Industrial Integration – Assurance Artifacts

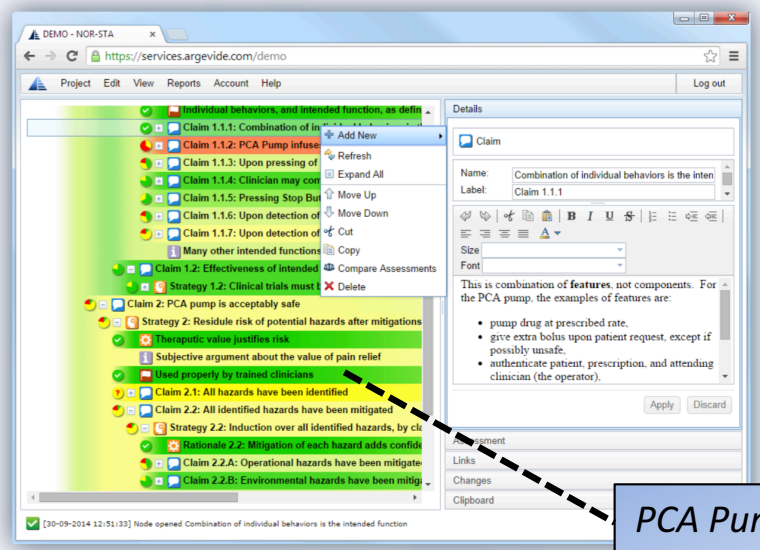
PCA Pump Assurance case originally developed under NSF FDA Scholar-in-Residence funding and now being extended on ISOSCELES is used by NOR-STA as one of the canonical examples in their training material

ARGEVIDE

www.argevide.com

Argevide NOR-STA features

- You can **develop** and **manage** large and complex argument structures.
- Tree view in NOR-STA facilitaties **browsing large arguments**.
- You can easily **copy and paste** fragments of the argument.
- You may use various options of **report generation.**
- NOR-STA is compliant with **ISO/IEC 15026** requirements.
- You can use OMG **ARM/SACM** import and export functions. Any ARM/SACM project can be easily imported to NOR-STA.
- When needed NOR-STA can generate **GSN** diagrams for your reports.



PCA Pump Assurance Case develop by KSU used in NOR-STA training

https://www.argevide.com/wp-content/uploads/2016/05/Argevide-NOR-STA-assurance-case.pdf

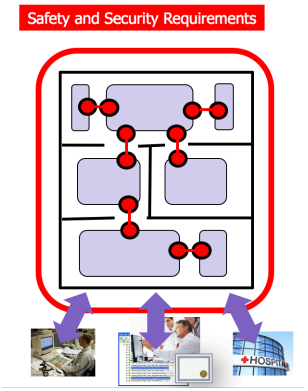
Alignment with Emerging Safety/Security Standards

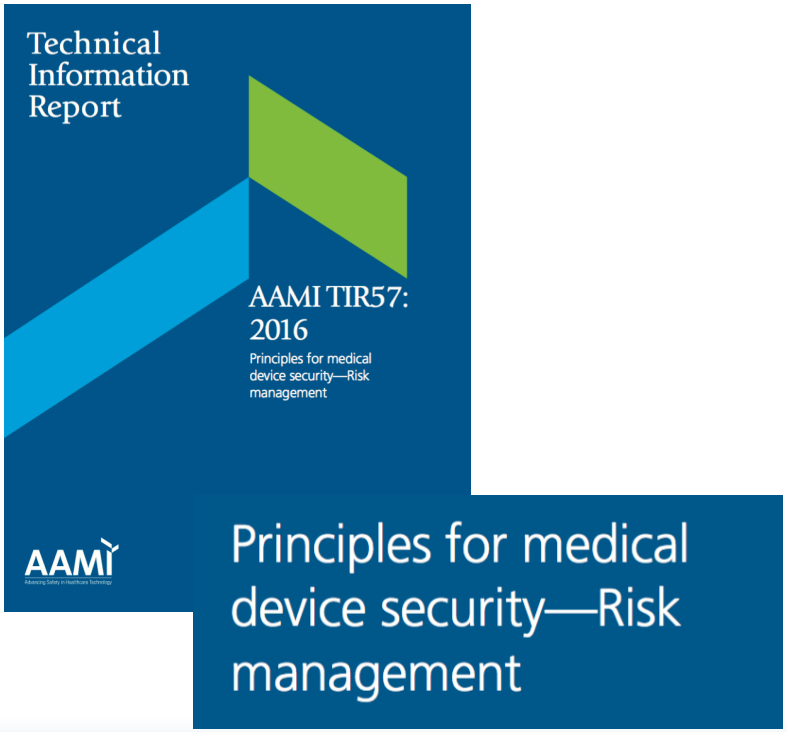
Cross-fertilization and deep integration with medical device safety/security standards that ISOSCELES team members and their close associates are involved in

- AAMI/UL 2800 family of safety/security standards for interoperable medical systems
  - Architecture, life-cycle processes, risk management (somewhat analogous to ISO 26262)
  - emphasis on ***platform-based engineering***
  - ISOSCELES team member Hatcliff is co-chair of primary working group; Vasserman leads security subgroup
  - ***Primary working example in 2800 support material is PCA Pump use case***
- AAMI TIR 57: Principles for medical device security – Risk Management
  - AAMI Security Group co-chair by Ken Hoyme from Boston Scientific (formally ISOSCELES PI from Adventium Labs)
- NIST Security Standards

AAMI
Advancing Safety in Healthcare Technology

Underwriters Laboratories





ISOSCELES Work Force Training Resources

The following indicates some of the support material posted on course/project web page to provide background information to students/researchers

PCA Pump in nutshell

- Patient Controlled Analgesia (PCA) Pumps: The Basics

PCA Clinical Tutorials from Columbia Gorge Community College

- PCA Introduction (http://www.youtube.com/watch?v=RAI5sPOAxqU)
- PCA Setup I (http://www.youtube.com/watch?v=RtWjHQN-wu8)
- PCA Setup II (http://www.youtube.com/watch?v=kXaMW754Hk4)
- PCA Initiation (http://www.youtube.com/watch?v=GDIoo___tkg)
- PCA Manage I (http://www.youtube.com/watch?v=GMbYHvgfY2U)
- PCA Manage II (http://www.youtube.com/watch?v=eYPrtxHG5e8)

Training videos for prep'ing and operating PCA Pump in a clinical context

Baxter PCA Pump Tutorial

- http://www.youtube.com/watch?v=KqGCOLIgIqE

PCA Clinical Guidelines

- *Patient-Controlled Analgesia: Making it Safer for Patients* , Cohen et al. (.pdf)
- *Patient-Controlled Analgesia: Guidelines of Care*, San Diego Patient Safety Taskforce (.pdf)
- *Acute Post operative Analgesia Guidelines: Patient Controlled Analgesia*, Royal Cornwall Hospitals, UK (.pdf)
- *Patient Controlled Analgesia (PCA) Policy for Adult and Paediatric Patients*, West Hertfordshire, UK (.pdf)

Industry/Clinical safety guidelines for PCA management

PCA Pump Prescription Forms and Drug Dosage

- Physician's Order Form -- New Hanover Regional Medical Center (.pdf)
- Physician's Order Form -- Overlake Hospital Medical Center (.pdf)
- Physician's Order Form -- St. Luke's Hospital (Chesterfield, MO) (.pdf)
- Morphine Dosage

Physician Order Forms for PCA Infusion

PCA Pump Prescription Auto-Programming

- *From Smart Pumps to Intelligent Infusion Systems – The Promise of Interoperability*, Patient Safety and Quality Health Care, May/June 2014. (.pdf)

PCA Pump Product Spec Sheets and Marketing Materials

- ambBIT ambulatory pump from Summit Medical Products, Inc. (marketing spec sheet, product web site)
- Alaris SE Pump (user manual, technical service manual)
- CADD-Prizm Ambulatory Infusion Pump (general description, clinician information, technical manual)

Example PCA Pump product operating and service manuals

PCA Pump Problems

- Mary E. Burkhardt's keynote presentation at the conference "Improving Medication Safety Through Effective Communication and Teamwork." (http://www.youtube.com/watch?v=wY3YyyQjvtQ)
- Paolo Masci's presentation on user interface oddities and problems in infusion pumps. (https://www.youtube.com/watch?v=T0QmUe0bwL8)

Improving Pump Safety via Monitoring of Respiratory Health

- A story about a loss of life and motivation for dedicated monitoring for PCA pumps using capnography (http://www.youtube.com/watch?v=gNZbvs3aByc)
- Medical Device Plug-n-Play Project's overview of using the Integrated Clinical Environment (ICE) to implement a safety-interlock for a PCA pump based on capnography and pulse oximetry monitoring. (http://www.mdpnp.org/MD_PnP_Program___Clinical_S.html) (see the videos under Scenario #1)
- Clinical study on PCA monitoring -- Maddox et al. "Continuous Respiratory Monitoring and a `Smart' Infusion System Improve Safety of Patient-Controlled Analgesia in the Postoperative Period." (.pdf)
- Clinical study on PCA monitoring -- Maddox et al. "Clinical Experience with Capnography Monitoring for PCA Patients." (.pdf)
- Clinical study on PCA monitoring -- Overdyk et al. "Improving Outcomes in Med-Surg Patients with Opiod-Induced Respiratory Depression." (.pdf)

Clinical studies on PCA safety issues

http://openpcapump.santoslab.org/node/1