Overview of AAMI Efforts and Open Issues in Medical Device Security

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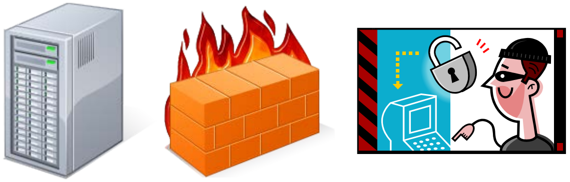
Medical Culture

The focus of hospitals and device manufacturers is on saving lives

Physical pharmacy security

Security focused on data privacy and protecting old software from infection



Experience says the attacker is either out for personal gain – drugs, fame, sellable information or it is non-targeted

"Faith-based" security risk assessment

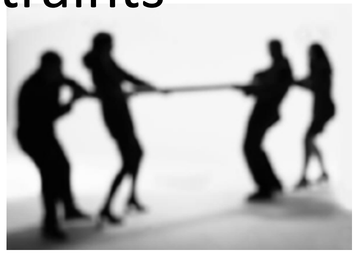
Many find it inconceivable that anyone would want to harm a sick patient

Developer Skill-sets

- Medical devices are cyber-physical systems
- Medical Device Security is much more than confidentiality of patient data – it is about safety

IT Security personnel are often missing:

- Real-time, embedded systems experience.
- Safety risk management culture.
- Regulated device constraints – Quality Systems.



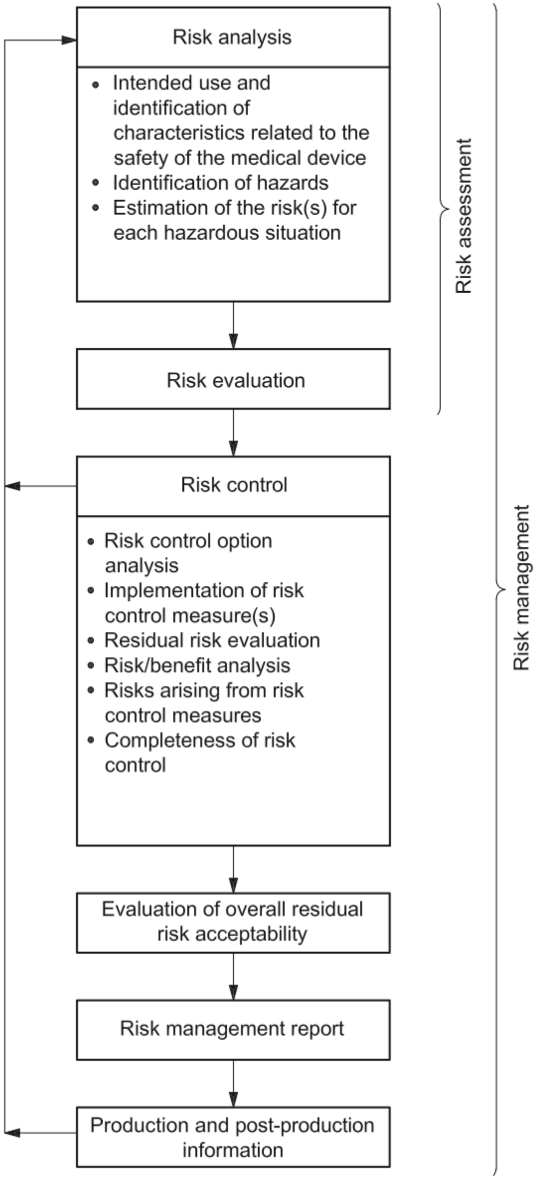
Medical device personnel are often missing:

- Understanding the subtle behaviors of security protocols.
- How to assess risk of future behavior of an adversary.
  - Safety risk management is very experiential/data driven.

Hybrid-skills or appropriately configured cross-functional teams are required

Medical Device (Safety) Risk Management

- "Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk" – ISO 14971
- Requires risk ranking
  - Between risks.
  - Individual acceptability.
  - Overall residual risk.



Risk analysis

- Intended use and identification of characteristics related to the safety of the medical device
- Identification of hazards
- Estimation of the risk(s) for each hazardous situation

Risk evaluation

Risk control

- Risk control option analysis
- Implementation of risk control measure(s)
- Residual risk evaluation
- Risk/benefit analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual risk acceptability

Risk management report

Production and post-production information

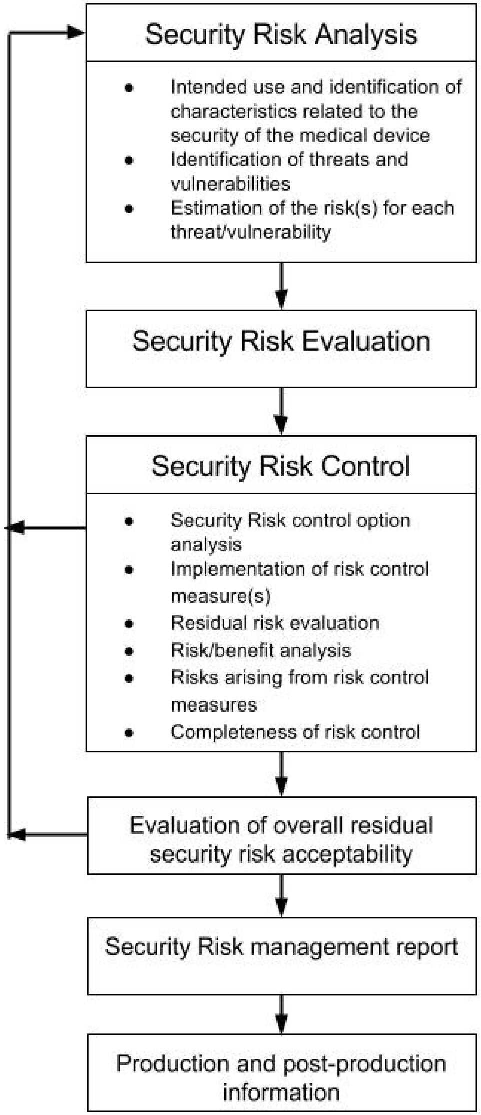
Risk assessment

Risk management

AAMI – Device Security Working Group

- Developing guidance document for applying ISO 14971 to device security risk management
  - Terminology.
  - Security risk management in ISO 14971 context.
  - Security best practices.
- Group was formed in May 2013
- Driving to early 2015 release

AAMI TIR - Security Risk Management



Security Risk Analysis

- Intended use and identification of characteristics related to the security of the medical device
- Identification of threats and vulnerabilities
- Estimation of the risk(s) for each threat/vulnerability

Security Risk Evaluation

Security Risk Control

- Security Risk control option analysis
- Implementation of risk control measure(s)
- Residual risk evaluation
- Risk/benefit analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual security risk acceptability

Security Risk management report

Production and post-production information

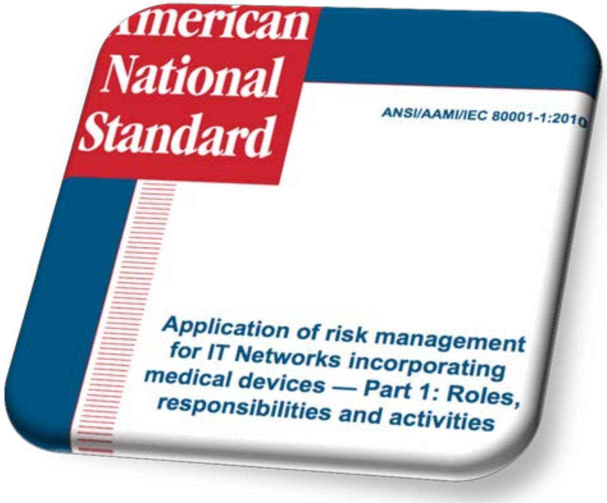
- Extend the assessment of risk to incorporate sources that arise from loss of device security
- Main body parallels the requirements sections of ISO 14971
- Specific focus on risk assessment
  - Likelihood/Attractiveness
  - Severity/Impact
- Strong ties to NIST SP800-30r1

AAMI TIR – Best Practices

- Documenting best practices with significant set of references
  - Focusing on medical device specifics as much as possible.
- Organized along the following main themes
  - How to assess security risk for a device.
  - Best practices for secure device design.
  - Best practices for device security testing.
  - Considerations for post-market surveillance, and particularly plans for security maintenance.

ANSI/AAMI/IEC 80001 Standards

- "Application of risk management for IT-networks incorporating medical devices"
- Defines roles and responsibilities of
  - "Responsible Organization"
  - Medical IT Integration Risk Manager
  - IT-Network Maintainer
  - Device Manufacturers
- 80001-2-2 addresses disclosure of device security characteristics
- Use is still mostly voluntary



merican National Standard

ANSI/AAMI/IEC 80001-1:2010

Application of risk management for IT Networks incorporating medical devices — Part 1: Roles, responsibilities and activities

Calibrating Safety and Security Risks

- Organizations must decide where to invest to reduce the greatest risks
  - Classic safety risks will compete with security risks for resources.
- Traditional risk models differ between domains
  - Quantitative vs. qualitative.
- Useful methods for calibrating different risk models are lacking

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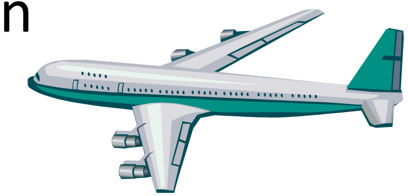
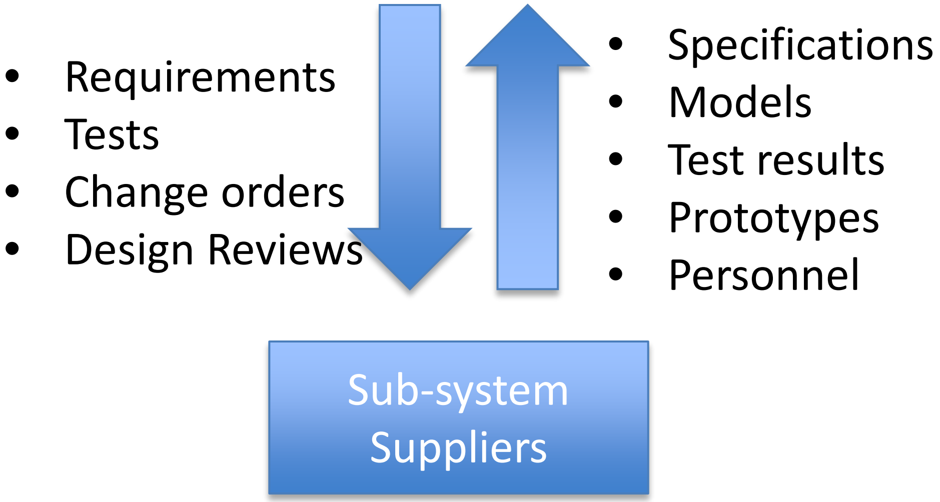
Challenge: Hospital Systems Integration

Aviation





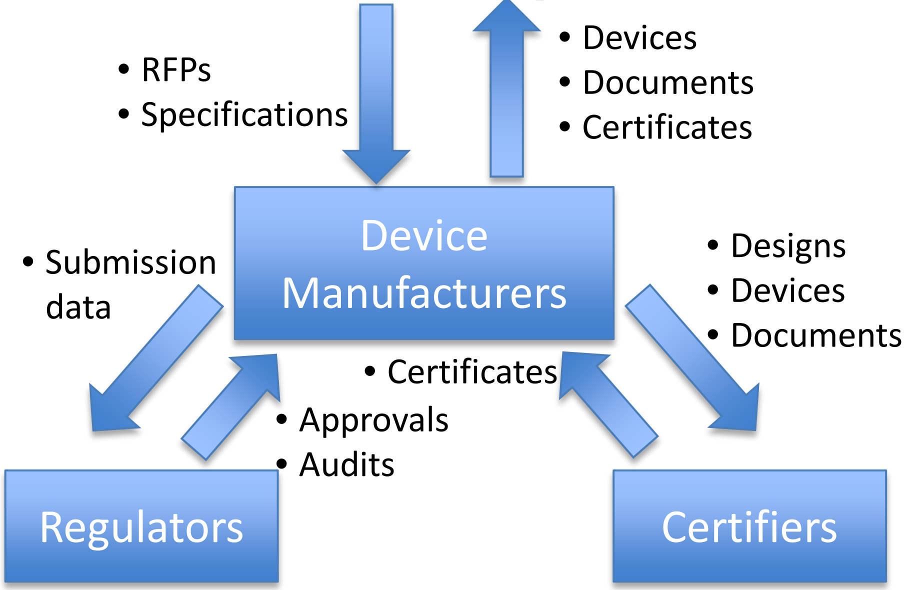
- Requirements
- Tests
- Change orders
- Design Reviews

- Specifications
- Models
- Test results
- Prototypes
- Personnel

Sub-system Suppliers

- Many standards used, but thoroughly verified at many levels

Health Care



- RFPs
- Specifications

- Devices
- Documents
- Certificates

Device Manufacturers

- Submission data

- Designs
- Devices
- Documents

- Certificates

- Approvals
- Audits

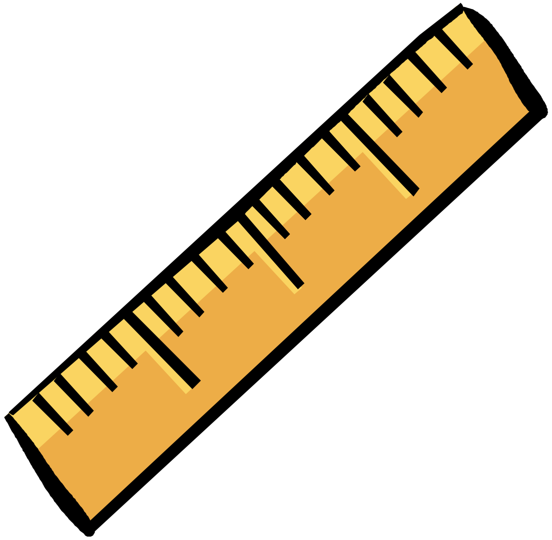
Regulators

Certifiers

- Standards implementation quality set by certifiers
- Approval cycles can inhibit change

Safe & Secure Hospital-integrated Device Networks

- What needs to be standardized to enable hospital device integration?
  - Message structures
  - Nomenclature
  - Mode logic
  - Timing, freshness, QoS
  - Security properties
  - Error behaviors – to faults and security events
  - …



- What tools are required?
  - "Plug and Play" versus analysis tools

AAMI/UL Joint Committee 2800

- Developing a family of standards to address safe medical device interoperability
- Three dimensions being evaluated
  - Definition of a JC2800-compliant architecture.
  - “Vertical” standards for specific problem domains – e.g. patient-controlled analgesia.
  - “Horizontal” standards to address safety, security, and other “ilities.”
- Still deciding how “deep” they go in standardized elements

Balancing Security and Usability in Clinical Use

- IEC 62366 addresses usability engineering processes for medical devices
  - Does not explicitly address device security.
  - Specific to the use of a single device.
- Clinical workflow
  - Team of people.
  - Multiple devices from different manufacturers.
  - Serving multiple patients in a work shift.
- Potential need for common security controls
  - And common means for access/logging in an emergency situation.

Summary

- AAMI addressing device security process for manufacturers
  - FDA Draft Guidance will drive its use.
- ANSI/AAMI/IEC 80001 addresses security processes for hospital networks
  - But its use is not generally required.
- There is a big educational need
- Medical Device Security Research needs include
  - How to create safe and secure device networks from the “bottom up.”
  - What security controls should be standardized to reduce user confusion?