

# GE Healthcare

## Medical Device Product Security

Patient Safety...Patient Privacy...Patient Care

Presentation to the:  
Information Security and Privacy Advisory Board  
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GE imagination at work



# Topics

GE Healthcare and the Healthcare Environment

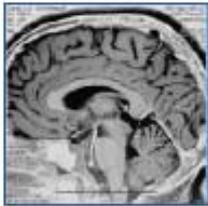
Medical Device Security Environment and Challenges

Improving Security within the Medical Device Environment

Moving Forward

# GE Healthcare

## Broad-based Technologies



Diagnostic imaging & surgery technologies



Clinical products



Medical diagnostics

## Information Technology



Integrated admin. & clinical



Electronic medical records

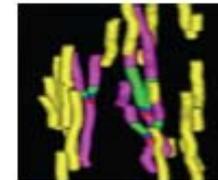


Picture Archiving System (PACS)

## Life Sciences



Biopharmaceutical solutions



Protein & cell sciences



Service

Our Purpose **At Work For A Healthier World**  
Our Strategy **Healthymagination**

## healthymagination

*A new business strategy to address global healthcare needs*



**Reduce the cost** of health procedures and practices through GE technologies and services



**Improve quality** and efficiency by simplifying ways of driving best standards of care



**Increase access** to better health for more people through low-cost innovation, education, and financing

**\$6 billion commitment to make health sustainable**



GE imagination at work

## healthymagination

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# Where does cybersecurity fit?



# Medical Device Security Environment

## Growing Government and Customer interest...

HIPAA, HITECH, and other laws creating growing security focus among healthcare providers, and cybersecurity getting more attention in Congress – “Cyber is a new domain of vandalism, crime, espionage, and, yes, warfare, but we are not very well equipped to deal with any of those challenges...we need to act to improve our security.” Rep Mac Thornberry, Feb 11, 2011

## FDA recognizes security relationship to patient safety...

FDA Guidance issued 2005 on manufacturer’s responsibility for addressing cybersecurity vulnerabilities as integral to ensuring the safety and effectiveness of the device within the requirements of the Quality System Reg.

## But security features can introduce new risks...

“Our concern for products is: Are they safe and are they effective? We don’t weigh in on security per se, but on measures like encryption that might affect or could have an impact on product safety and effectiveness, we might look



GE Intelligent Infrastructure

— Karen Riley, FDA Spokesperson (Boston Globe, July 5, 2010)

# Security Touch Points and Challenges

Product Security

**Product Design** - making new products secure



Long Product Life Cycles (20 yrs+)

Emphasis on clinical functionality

**Product Installed Base Support** – enhancing our existing products



Patch/Anti-Virus = design change  
Design changes require validation

Service Ops

**Service Technology** – remote service operations



Focus on accessibility and uptime

Reliance on remote monitoring

**Service** – supporting customer's privacy and security obligations



Large distributed workforce

New operational rigor needed



# Design Actions within the Quality System

## Rigorous design controls for new designs and design changes

- Validation ... “confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.” – a comprehensive process of testing, analysis, documentation, and review
- Risk Management...looks at severity of harm and probability of occurrence...considers failure modes and expected user error...defines a threshold for action

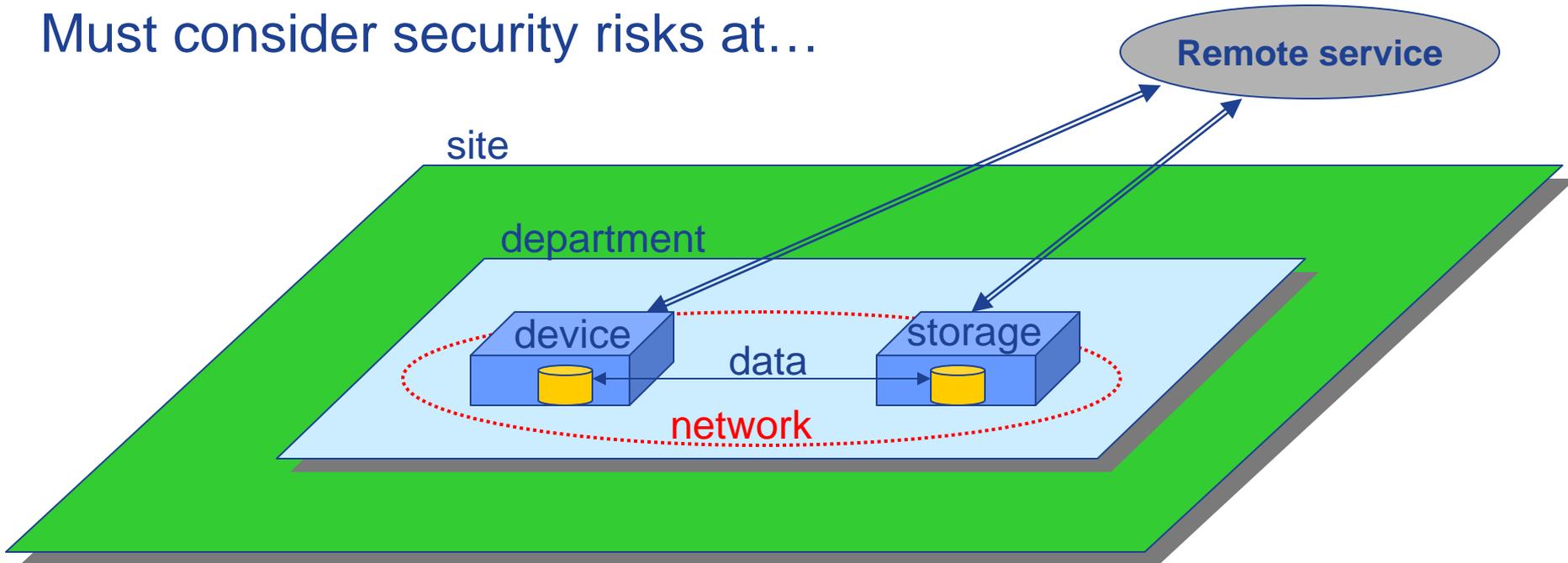
Changes add risks: FDA study shows 79% of software defects that resulted in product recalls were introduced by changes

Validations are not days, but rather weeks or months of effort

No safe harbor for adverse events caused by security

# Layered Security in Healthcare

Must consider security risks at...

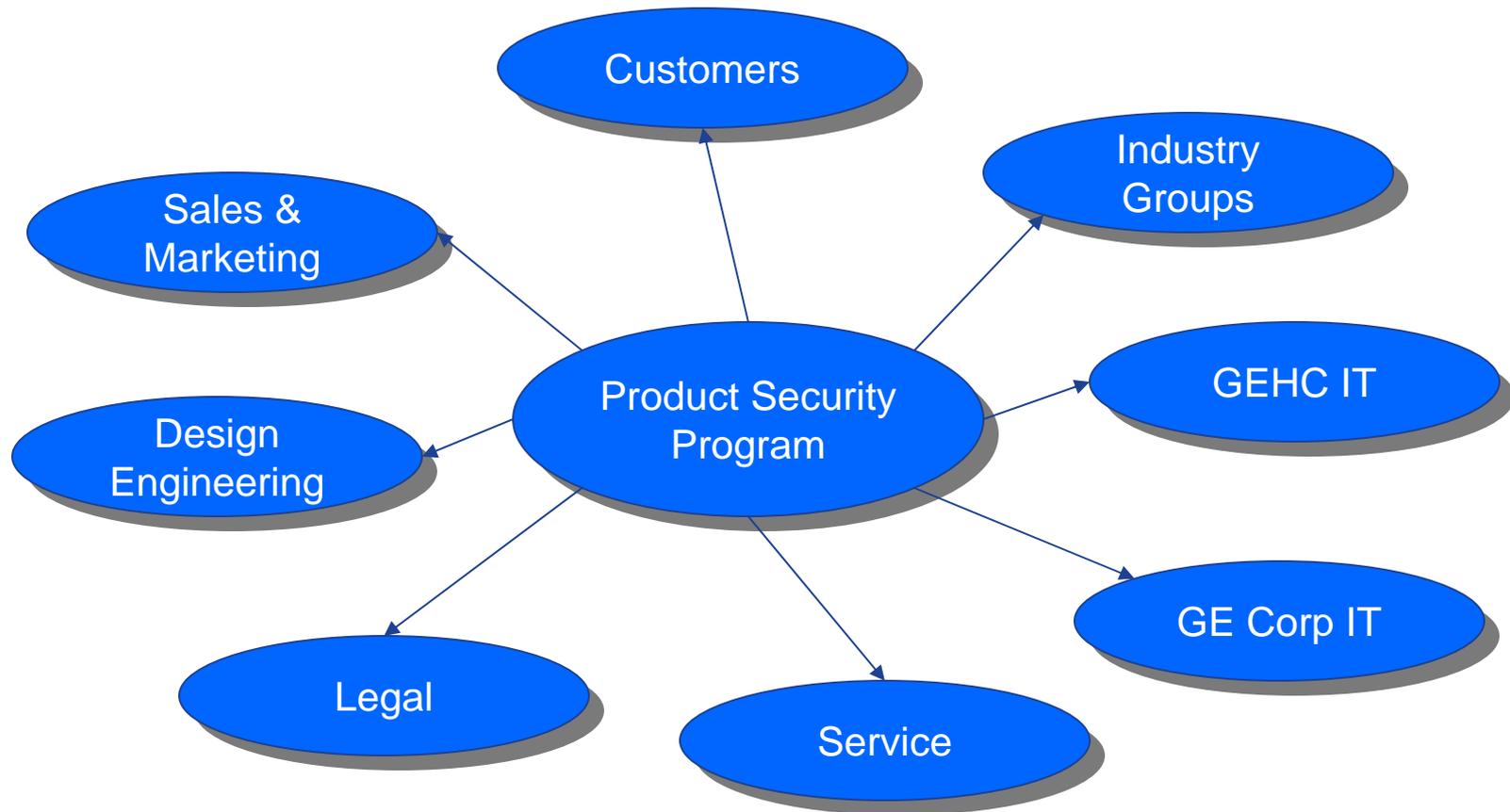


Security at each layer must work together

Device manufactures do not have visibility to all security risks and mitigations

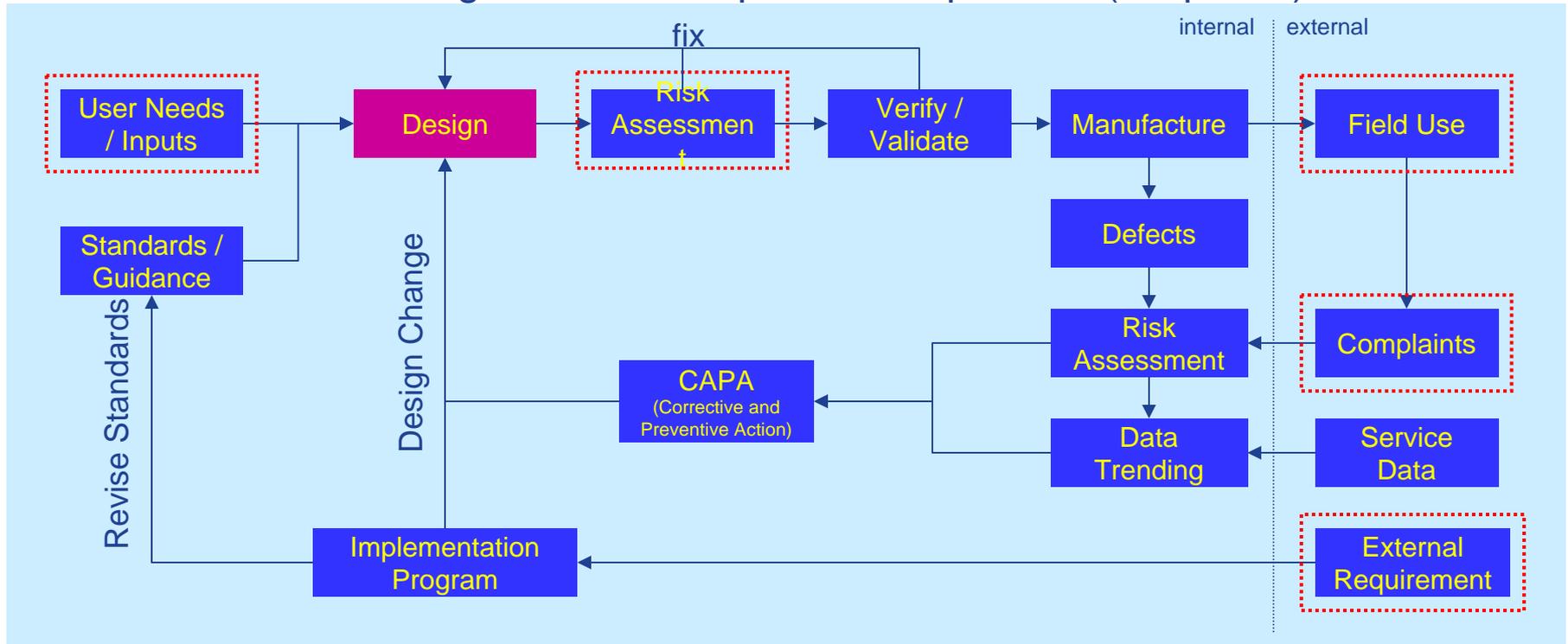
# Working Toward Improved Security

## Building the Security Team at GEHC:



# Integrating Security with Design

The medical device design continual improvement process (simplified):



Product  
Security  
Influence Points

## Enhancing the Influence of Security:

**User Needs – expand beyond clinical needs to security needs**

**Risk Assessment – use scanning tools to recognize security risks**

**Field Use / Complaints – track customer security concerns**

**External Requirements – Focused implementation program**

# Medical Device Security: Moving Forward

Product Security is not “one-size-fits-all” across the broad spectrum of networked devices

Security programs must be consistent with risks and patient safety needs

A collaborative approach needed to address security standards within the various layers: site, department, network, device

Safety and security – collaboration, not competition