Aligning Agile/SAFe® with A System Engineering Process Model

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- 23 years medical device software & system development
- Author/owner/user of SOPs & Work Instructions for software and systems development
- ASQ Certified Quality Auditor, focusing on Design Controls, Risk Management, Complaint Handling
- 14 years Agile practitioner, Trainer, Agile Transformation Coach, Certified Scrum Master, Certified SAFe® Program Consultant
- Lead author of AAMI TIR45 “Guidance on the use of AGILE practices in the development of medical device software” - Lead instructor for AAMI course on TIR45
- Adjunct Instructor for Design Control courses in St. Cloud State’s Master of Technology Quality program
- Consultant to large & small medical device organizations

Agile is Not Just for Software

- Scrum is used in many product-development contexts
- Agile Scaling concepts and frameworks address big system development
  - And integration of software teams using Agile with other development teams that may / may not be
- Scaled Agile Framework® (SAFe®)
  - Version 4.0 puts more emphasis on development of systems, aligning with Systems Engineering principles
  - For “large-scale, multidisciplinary software and cyber-physical systems”

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Software development is not just Software Engineering

- Embedded software connects with products/subsystems created by other engineering disciplines
- Big “software-only” systems need discipline of Systems Engineering

- “The Systems Engineering Engine”
  - NASA Systems Engineering Handbook provides a model of activities for developing big systems

Agile + Systems Engineering

- Agile (SAFe® + Scrum + XP + Kanban + …)

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- Systems Engineering concepts

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- A really good thing

SAFe® content from Scaled Agile Inc

(Content to follow includes publicly available information from Scaled Agile Inc. Used here with permission.)

- The “Big Picture”
  - http://scaledagileframework.com
- “SAFe® 4.0 in 8 Pictures”
  - http://scaledagileframework.com/videos-and-presentations/

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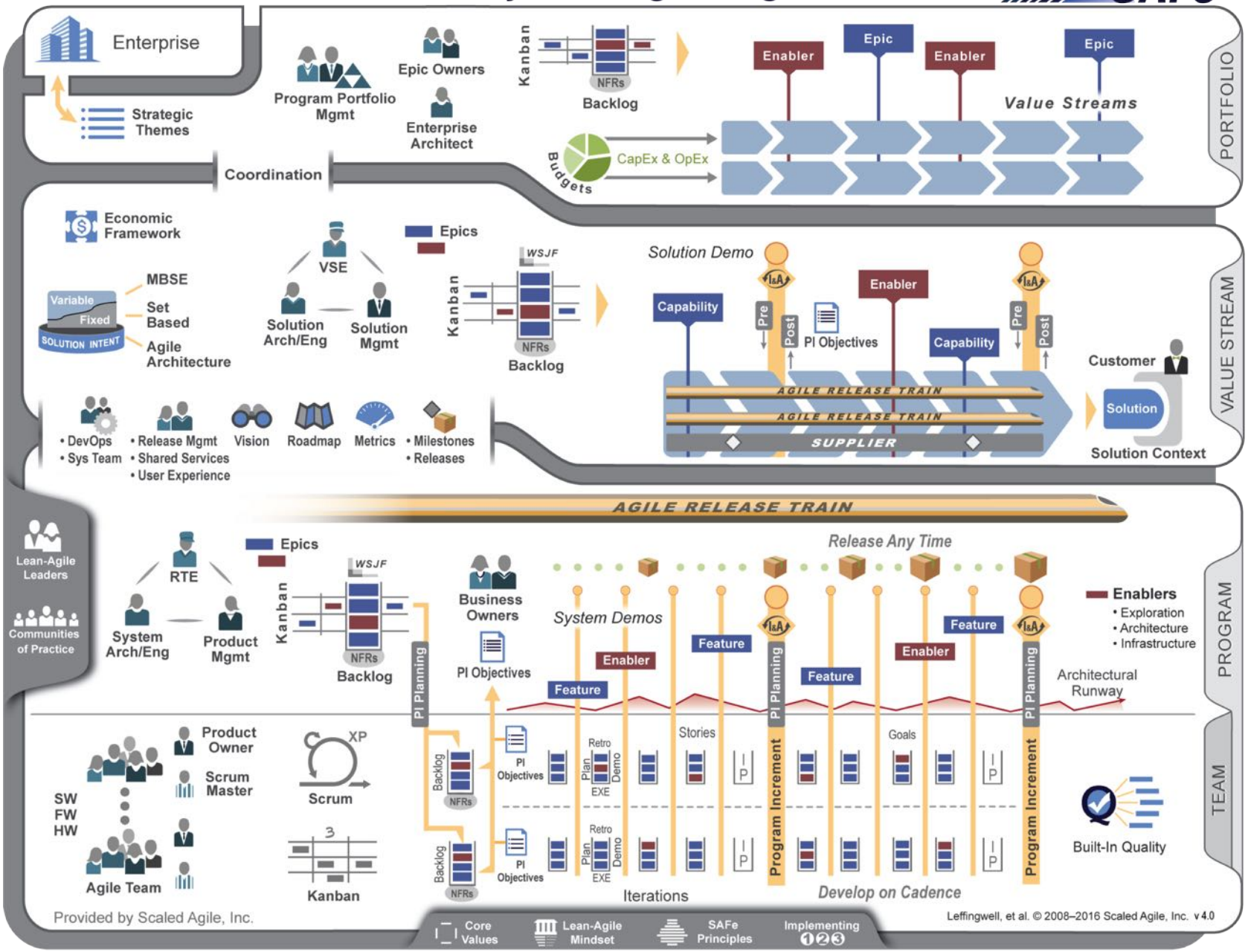
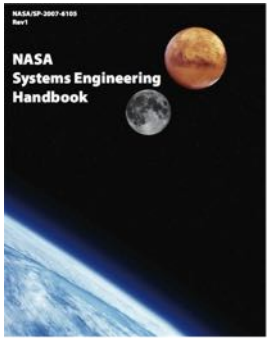
SAFe® 4.0 for Lean Software and Systems Engineering



NASA SE Handbook



Requirements flow down from level above

Realized products to level above

SYSTEM DESIGN PROCESSES

Requirements Definition Processes
1. Stakeholder Expectations Definition
2. Technical Requirements Definition

Technical Solution Definition Processes
3. Logical Decomposition
4. Design Solution Definition

TECHNICAL MANAGEMENT PROCESSES

Technical Planning Process
10. Technical Planning

Technical Control Processes
11. Requirements Management
12. Interface Management
13. Technical Risk Management
14. Configuration Management
15. Technical Data Management

Technical Assessment Process
16. Technical Assessment

Technical Decision Analysis Process
17. Decision Analysis

PRODUCT REALIZATION PROCESSES

Product Transition Process
9. Product Transition

Evaluation Processes
7. Product Verification
8. Product Validation

Design Realization Processes
5. Product Implementation
6. Product Integration

Requirements flow down to level below

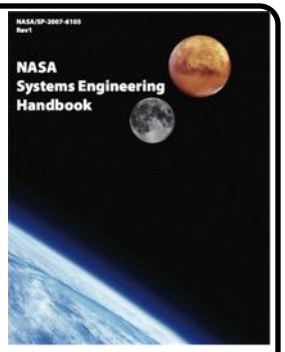
System design processes applied to each work breakdown structure model down and across system structure

Realized products from level below

Product realization processes applied to each product up and across system structure

Figure 2.1-1 The systems engineering engine

The Systems Engineering Engine



System Development Processes

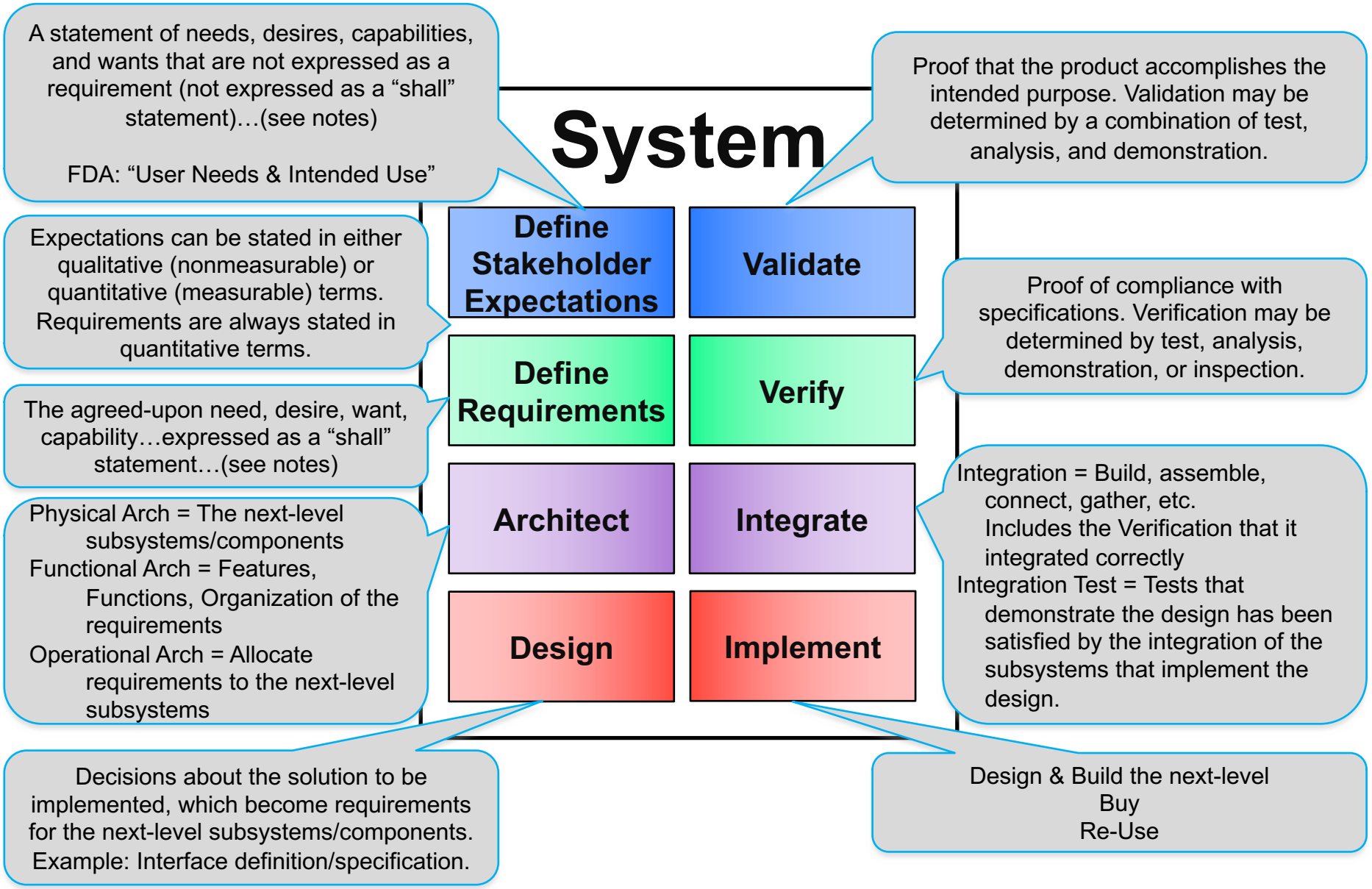
System Design	Product Realization
Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Integrate
Design	Implement

Technical Management Processes

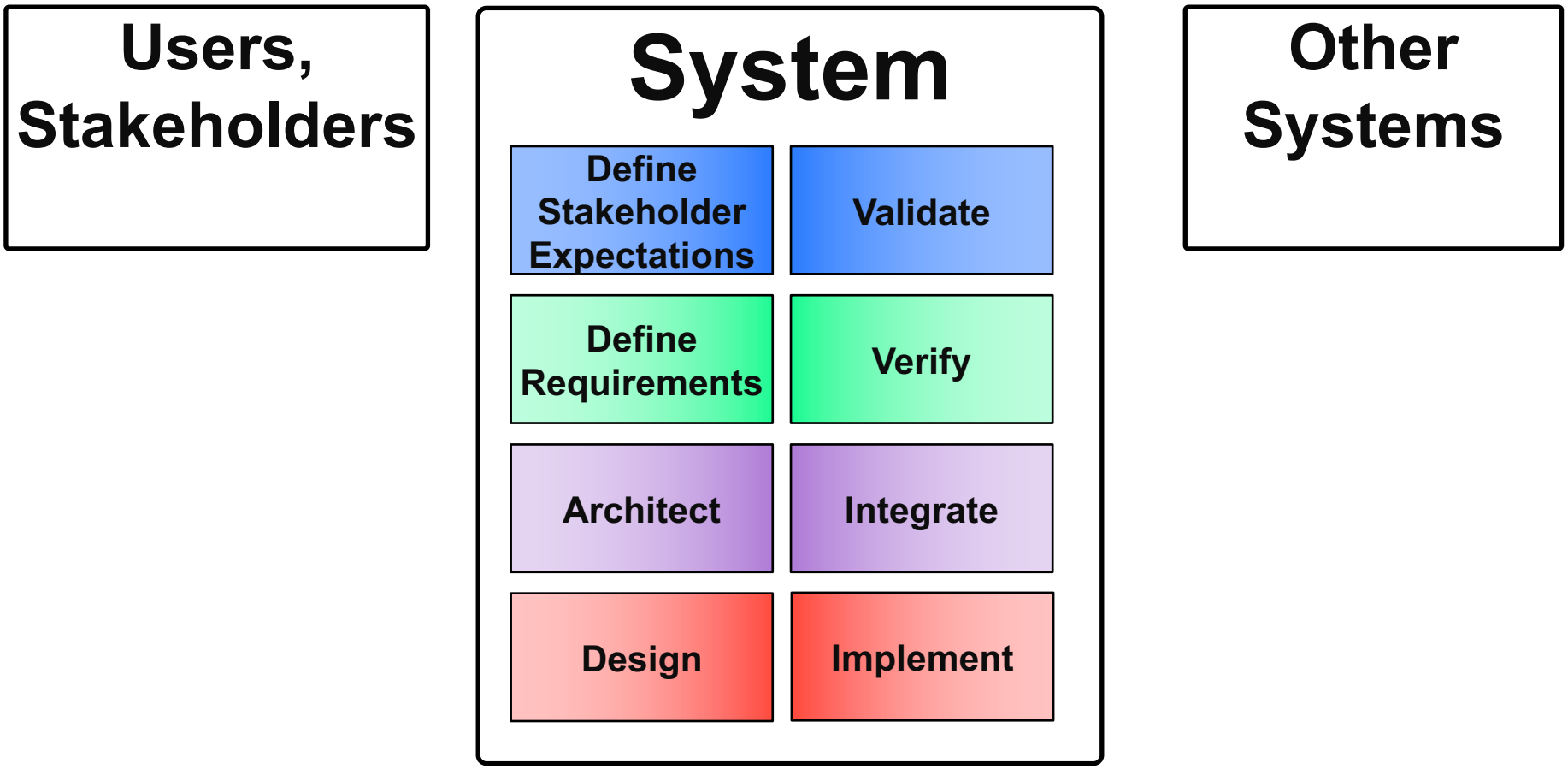
- Technical Planning
- Requirements Management
- Interface Management
- Risk Management
- Configuration Management
- Data Management

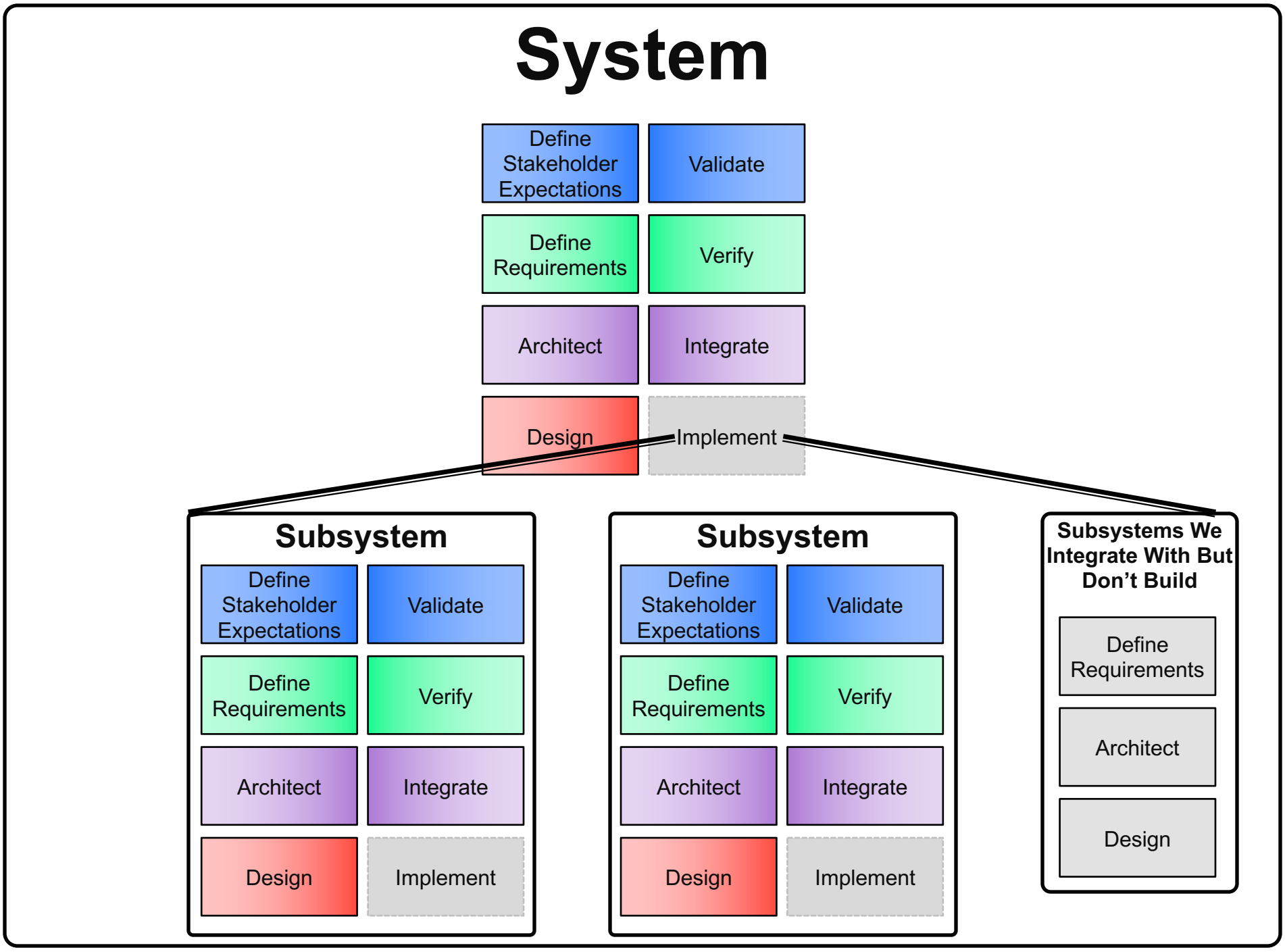
Adapted from: NASA Systems Engineering Handbook, NASA/SP-2007-6105

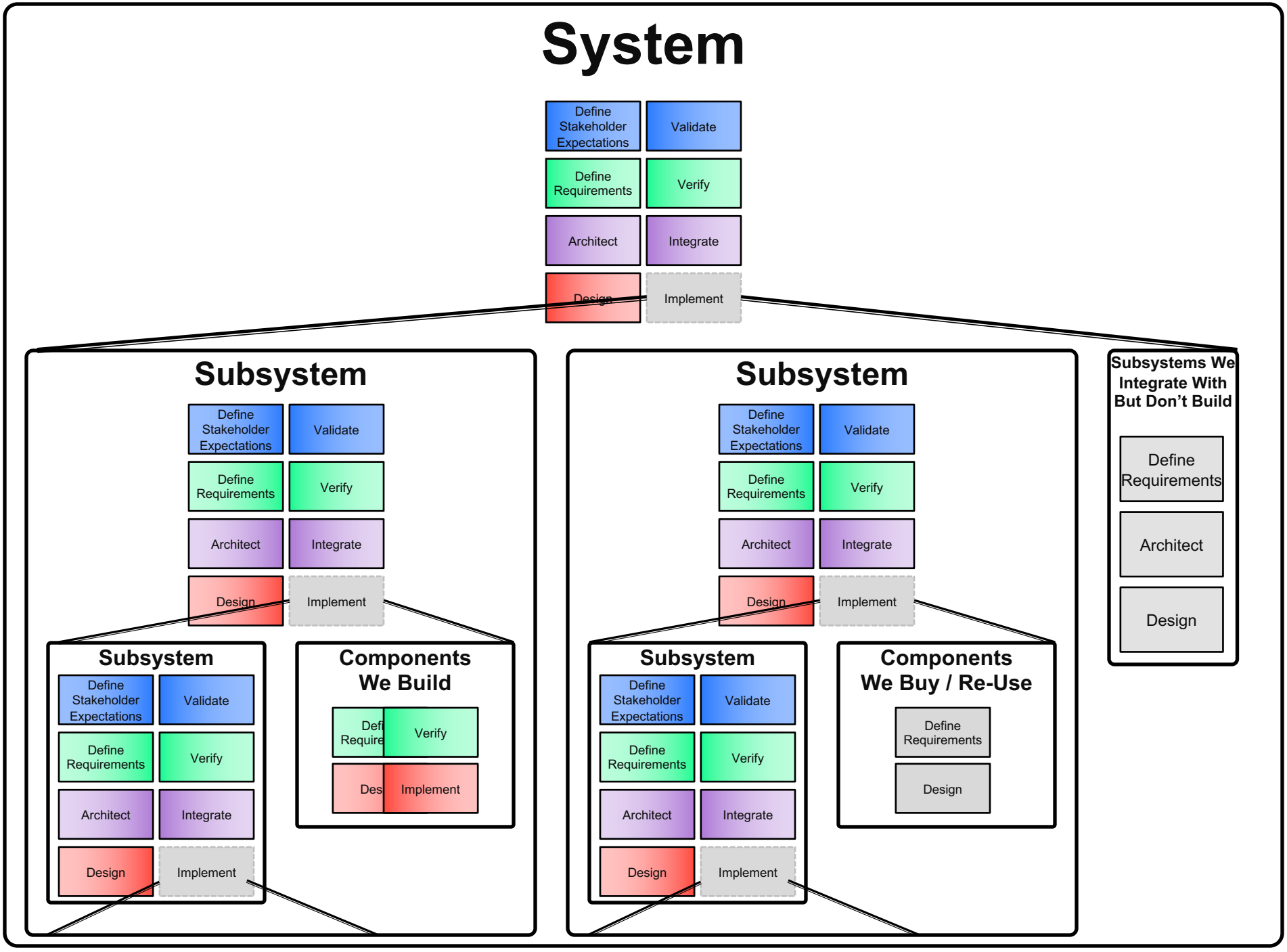
The Systems Engineering Engine



Systems Live Within A Context




System
Define Stakeholder Expectations
Validate
Define Requirements
Verify
Architect
Integrate
Design
Implement
Subsystem
Define Stakeholder Expectations
Validate
Define Requirements
Verify
Architect
Integrate
Design
Implement
Subsystem
Define Stakeholder Expectations
Validate
Define Requirements
Verify
Architect
Integrate
Design
Implement
Subsystems We Integrate With But Don't Build
Define Requirements
Architect
Design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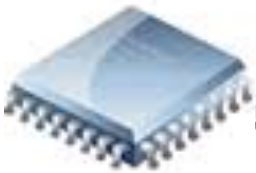
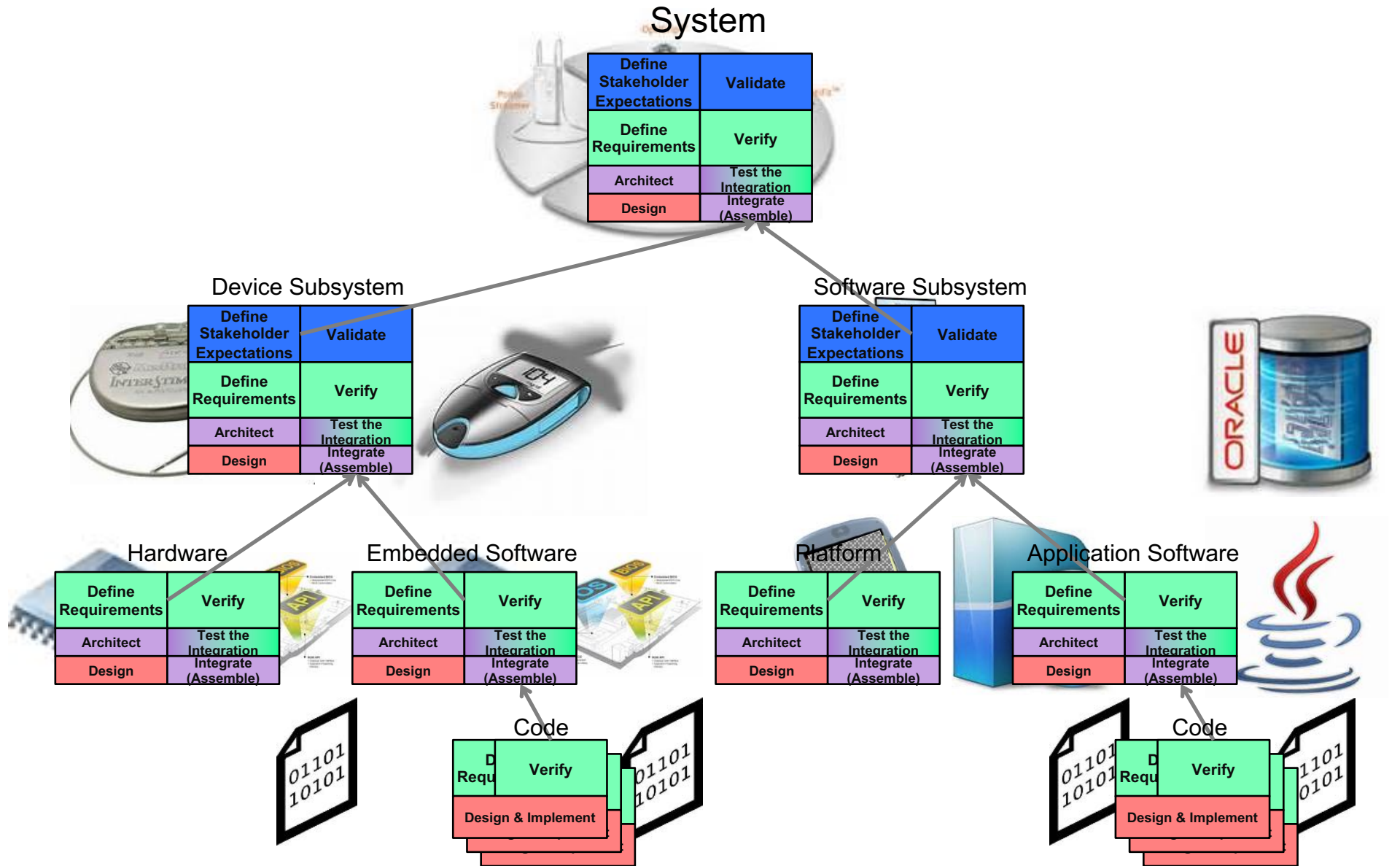
Implement
Subsystem
Define Stakeholder Expectations
Validate
Define Requirements
Verify
Architect
Integrate
Design
Implement
Components We Build
Verify
Implement
Subsystem
Define Stakeholder Expectations
Validate
Define Requirements
Verify
Architect
Integrate
Design
Implement
Components We Buy / Re-Use
Define Requirements
Design
Subsystems We Integrate With But Don't Build
Define Requirements
Architect
Design

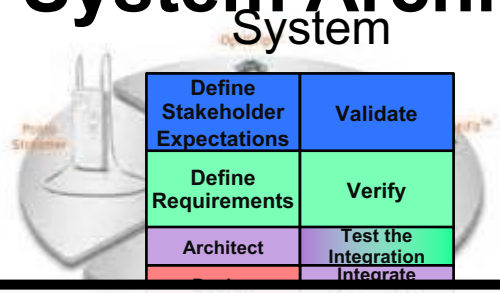
What is the System?



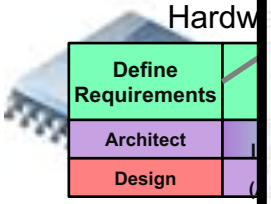
What is the System?
And What are the Activities & Deliverables?

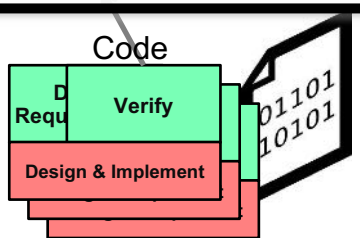


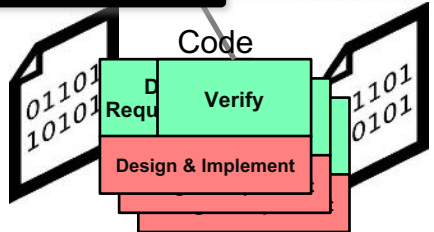
The System Development Activities and Deliverables are Determined by the System Architecture



- Determined by the Architecture – what is built
  - Physical (products in a catalog, components on a BOM)
  - Functional (features, capabilities)
- Determined by the Requirements – what is defined
  - How are the requirements/specifications organized?
  - What are they specifying?
- Determined by the Tests – what is verified
  - What are the tests verifying?
  - Where are tests executed?







The System
And The Activities to Create It

System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

Software Subsystem

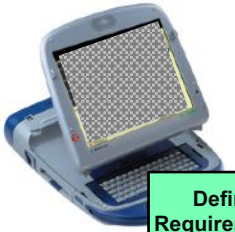
Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

Hardware

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

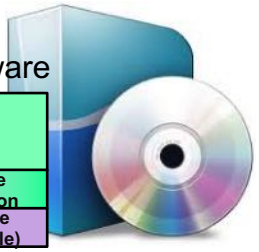
Embedded Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Platform

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Application Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

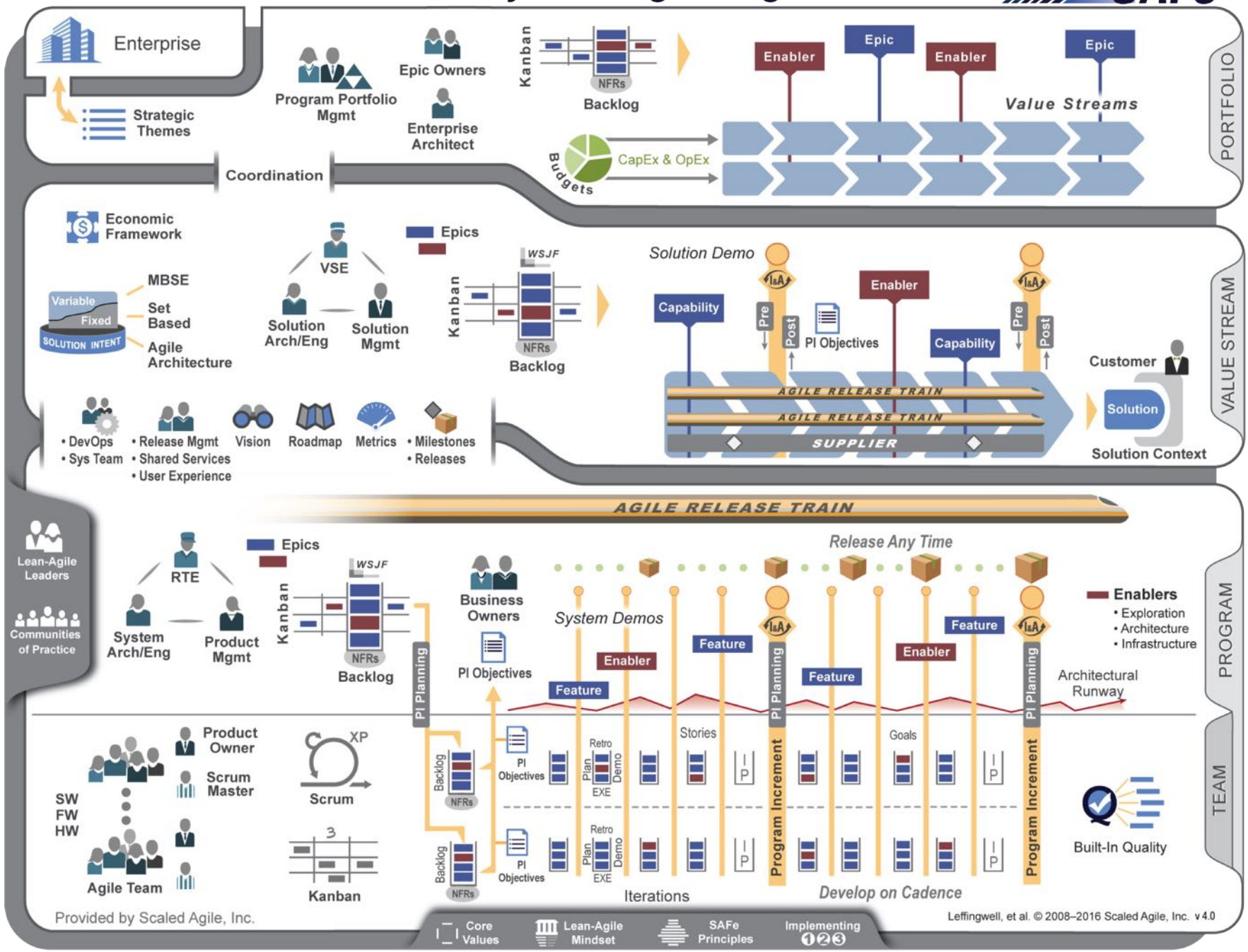
Code

Requ	Verify
Design & Implement	

Code

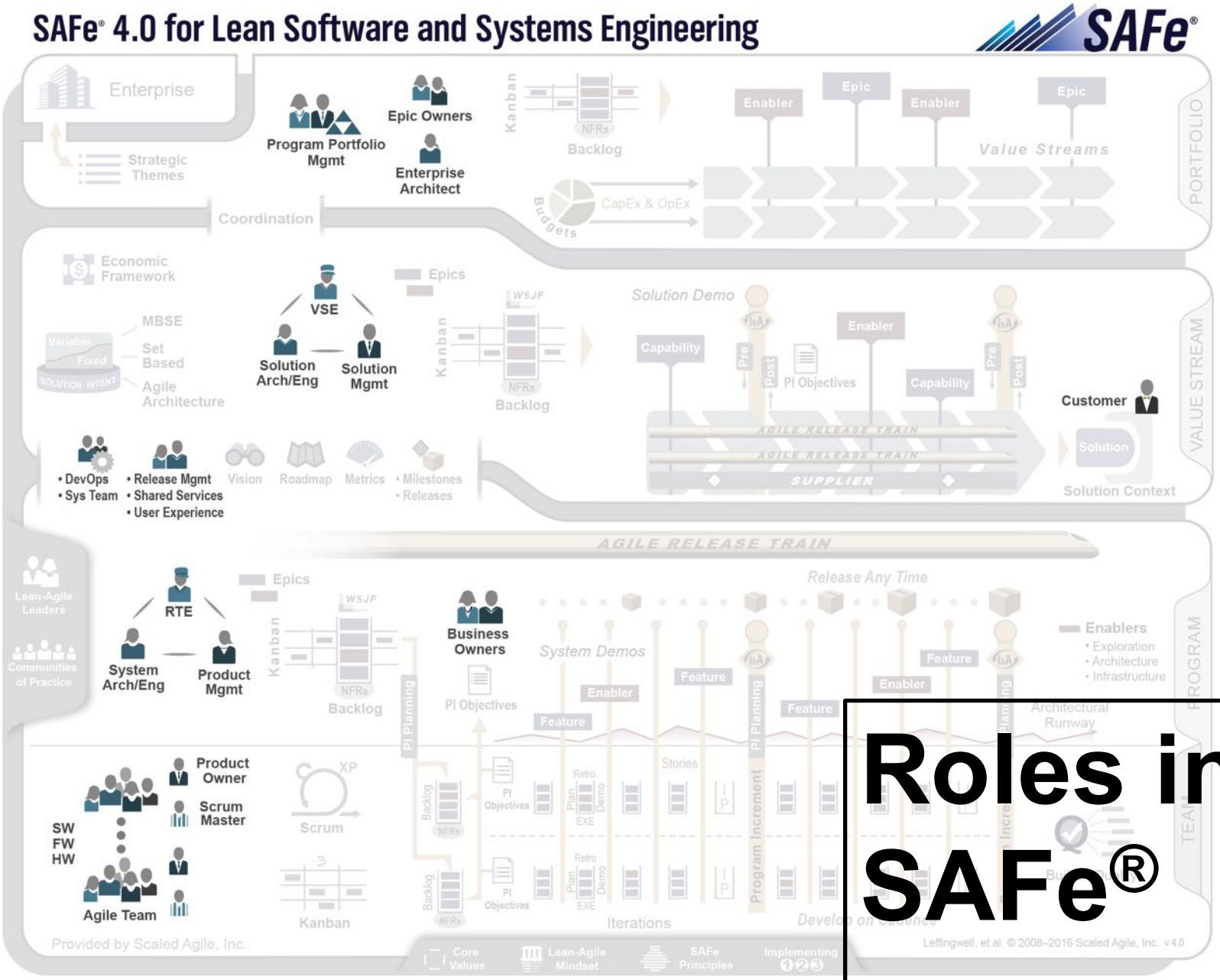
Requ	Verify
Design & Implement	

SAFe® 4.0 for Lean Software and Systems Engineering



Applying SAFe® to the Development of a System

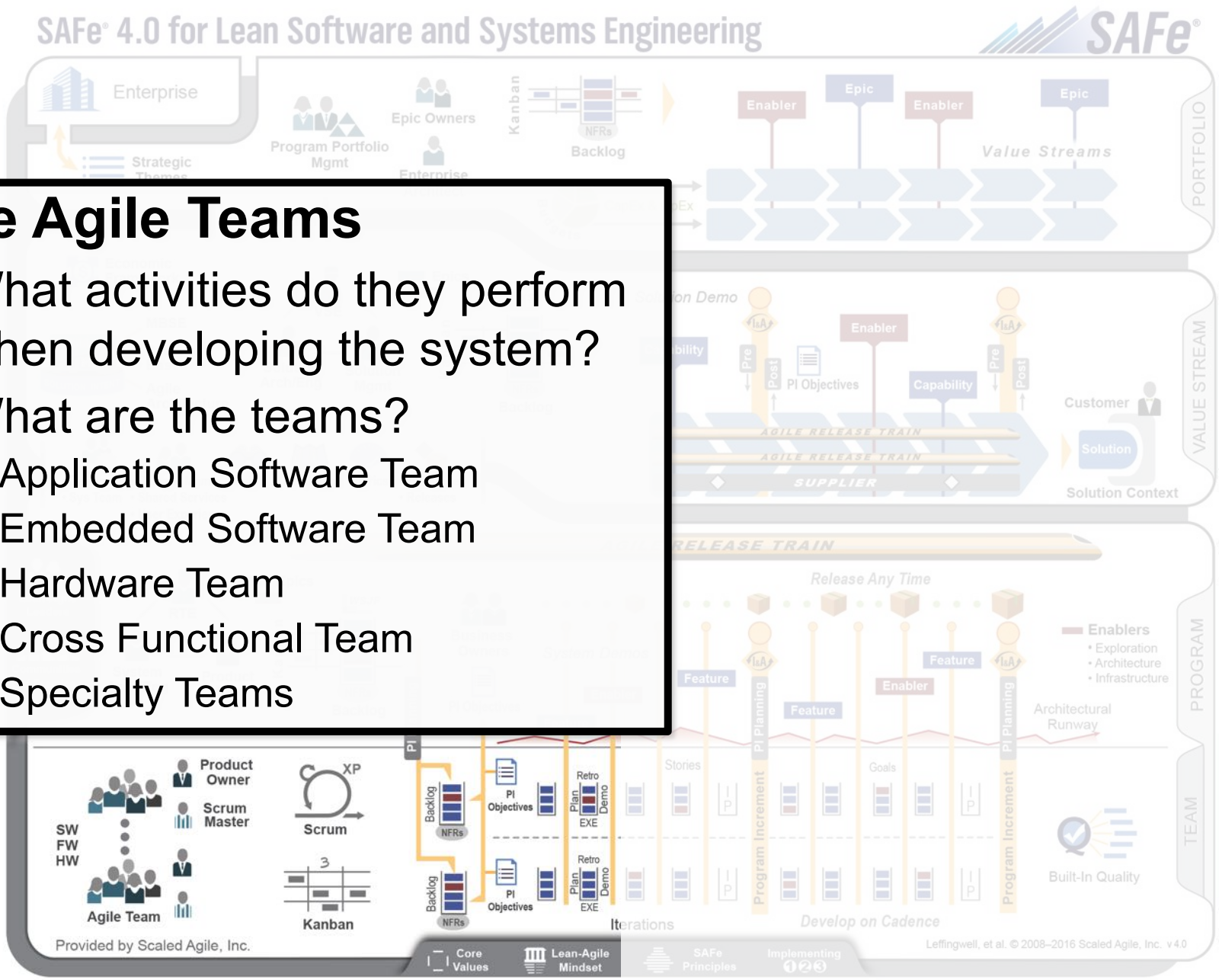
- What are the Teams?
  - What do they deliver?
  - What activities do they perform?
- What activities provide input to the teams?
  - And who does them?

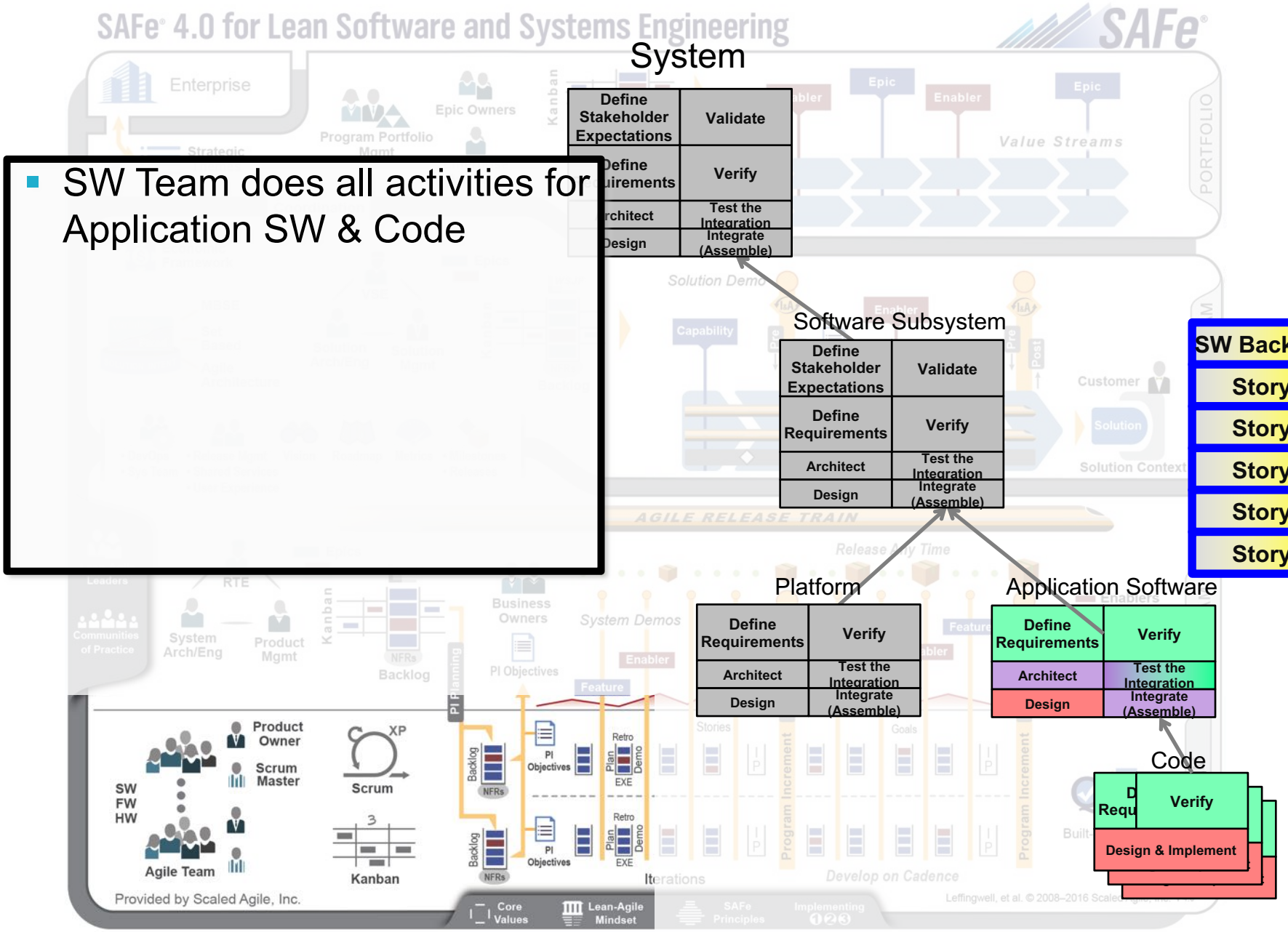


Roles in SAFe®

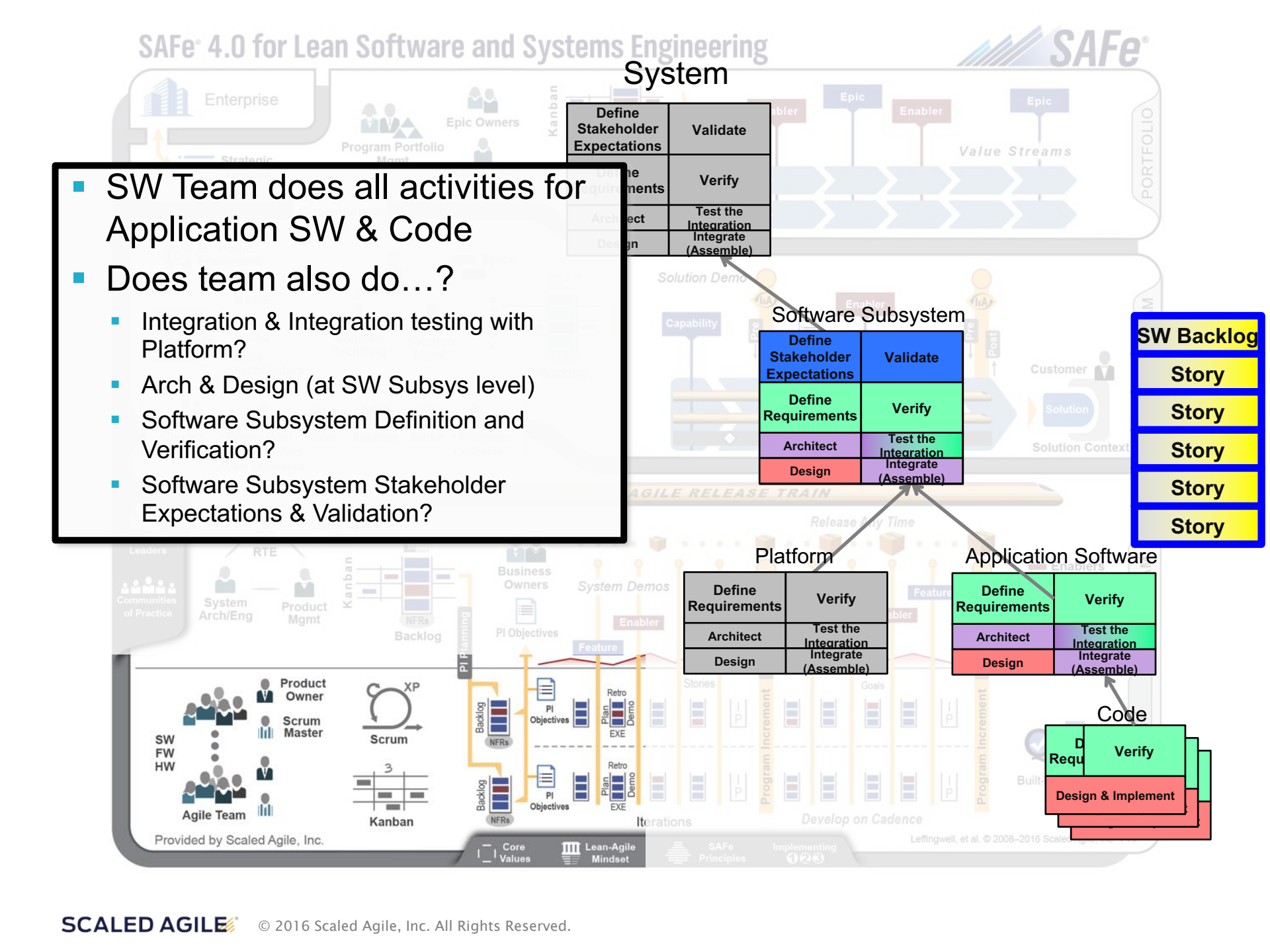
The Agile Teams

- What activities do they perform when developing the system?
- What are the teams?
  - Application Software Team
  - Embedded Software Team
  - Hardware Team
  - Cross Functional Team
  - Specialty Teams



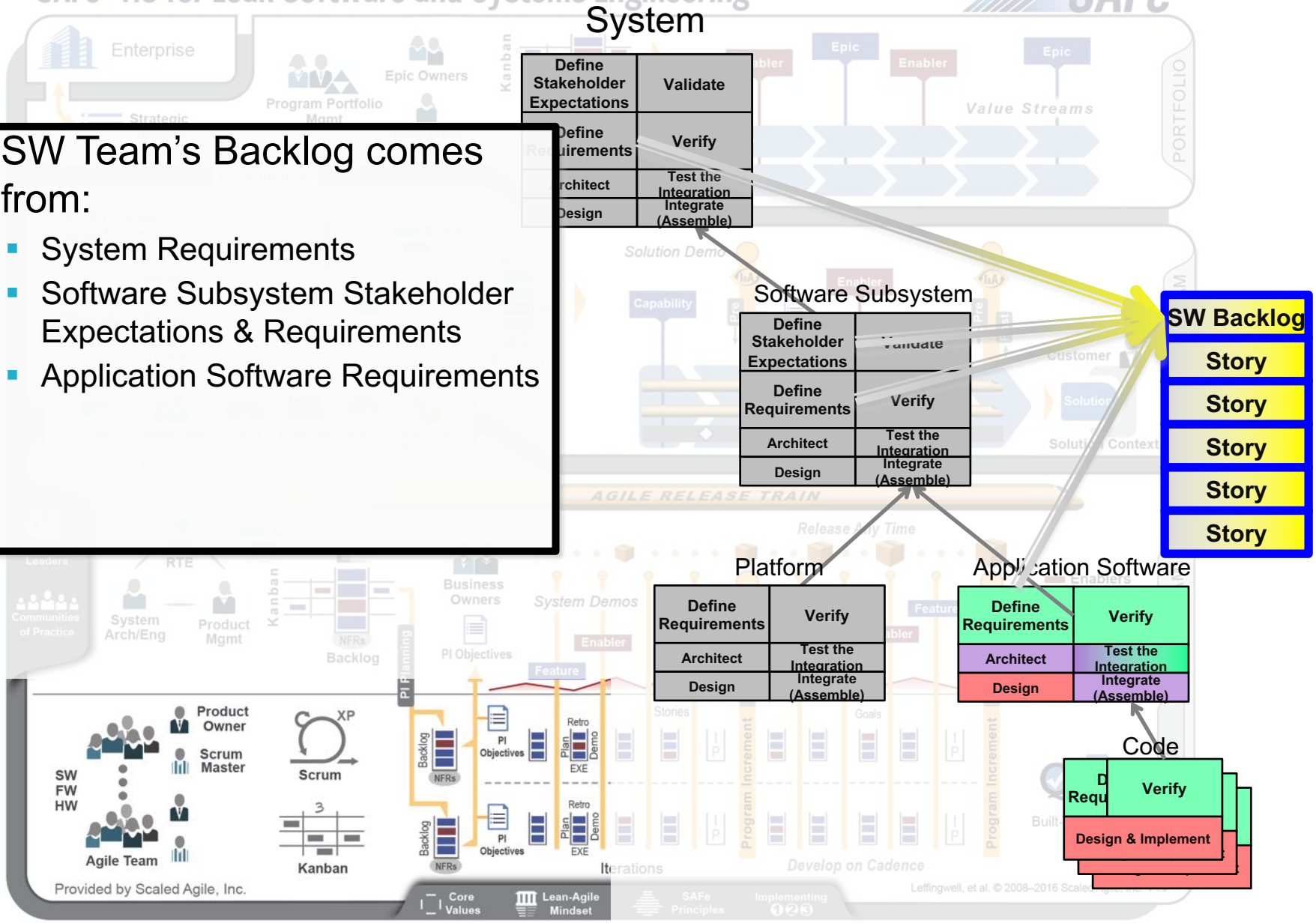


- SW Team does all activities for Application SW & Code

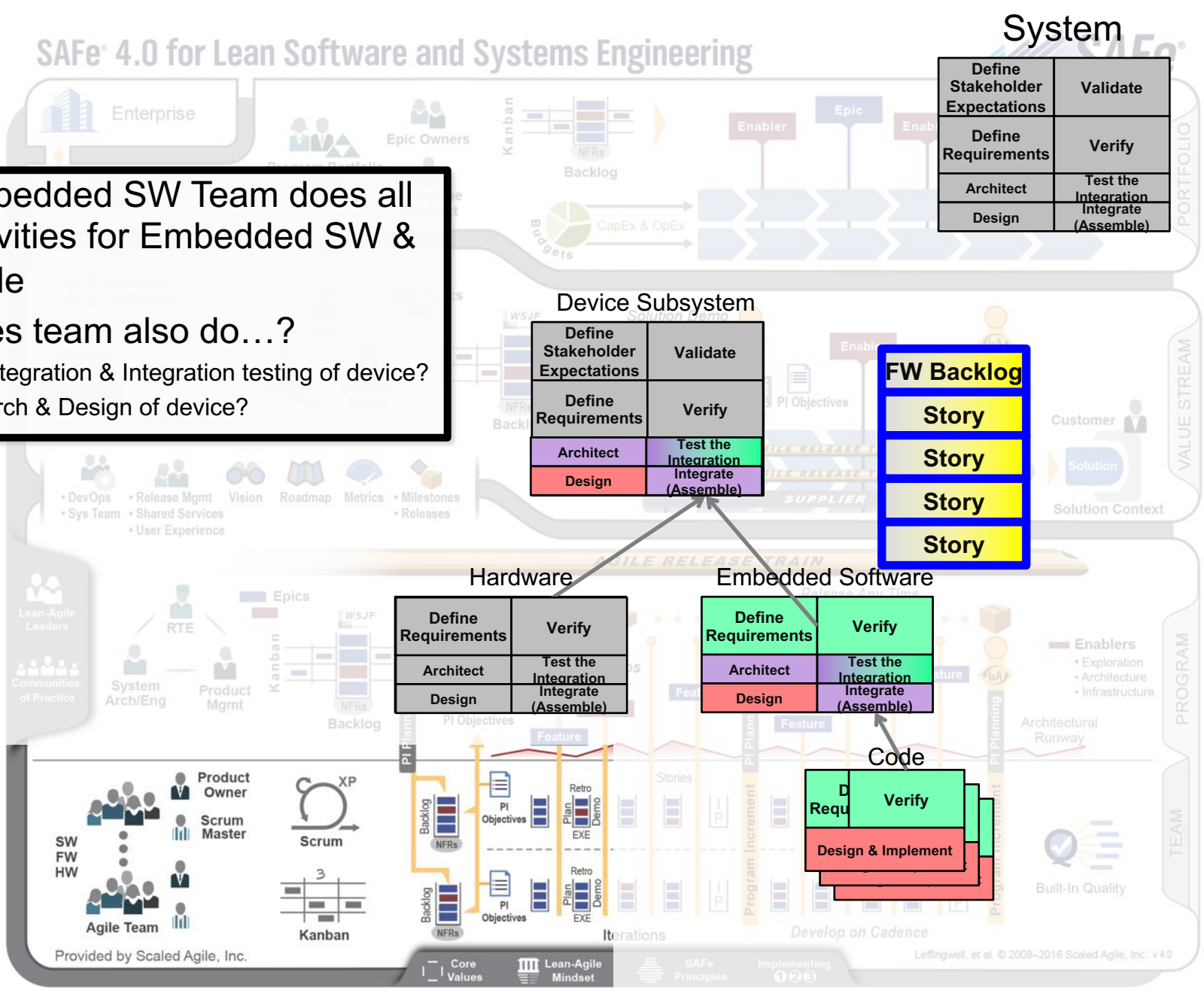


- SW Team does all activities for Application SW & Code
- Does team also do…?
  - Integration & Integration testing with Platform?
  - Arch & Design (at SW Subsys level)
  - Software Subsystem Definition and Verification?
  - Software Subsystem Stakeholder Expectations & Validation?

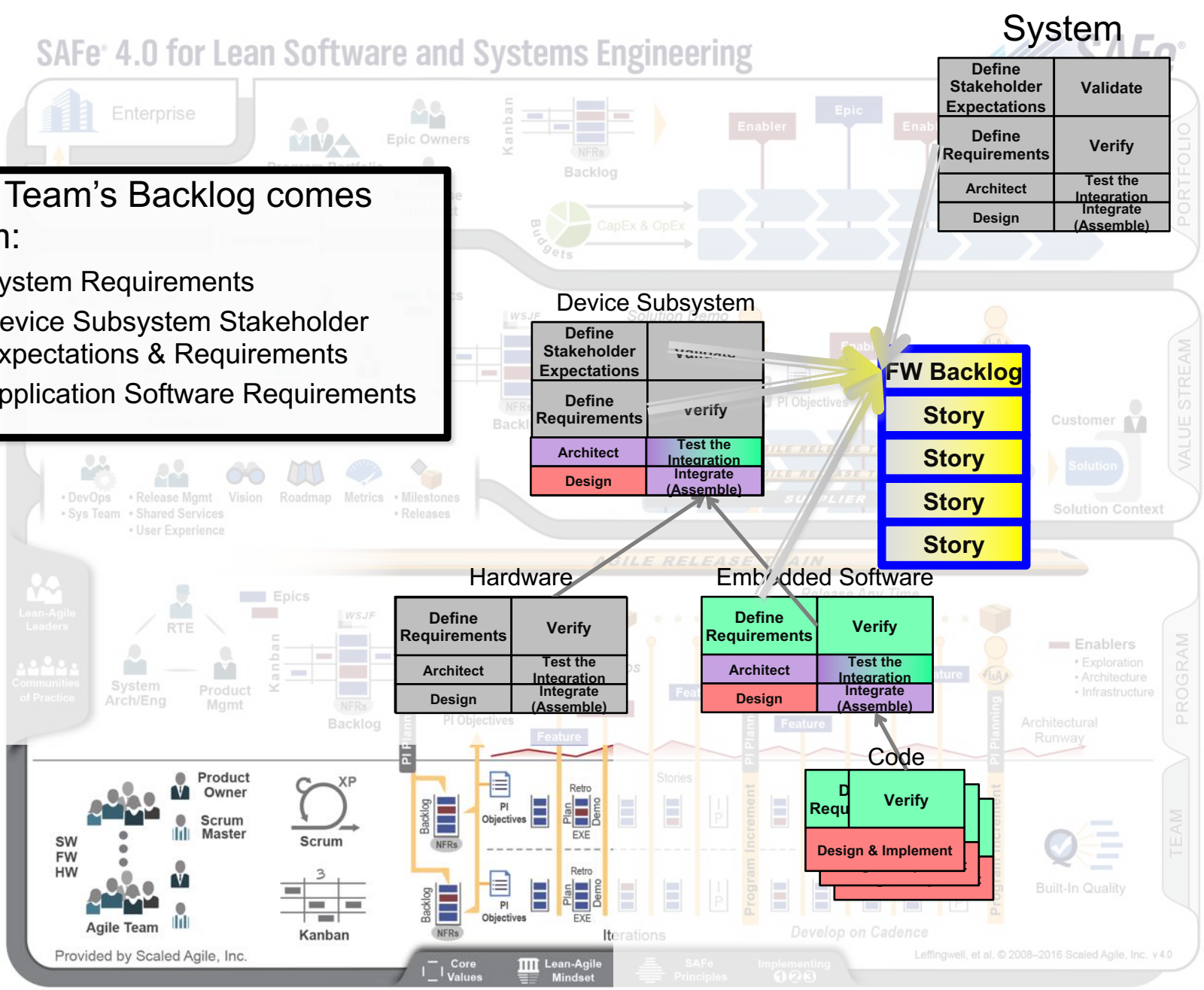
- SW Team's Backlog comes from:
  - System Requirements
  - Software Subsystem Stakeholder Expectations & Requirements
  - Application Software Requirements



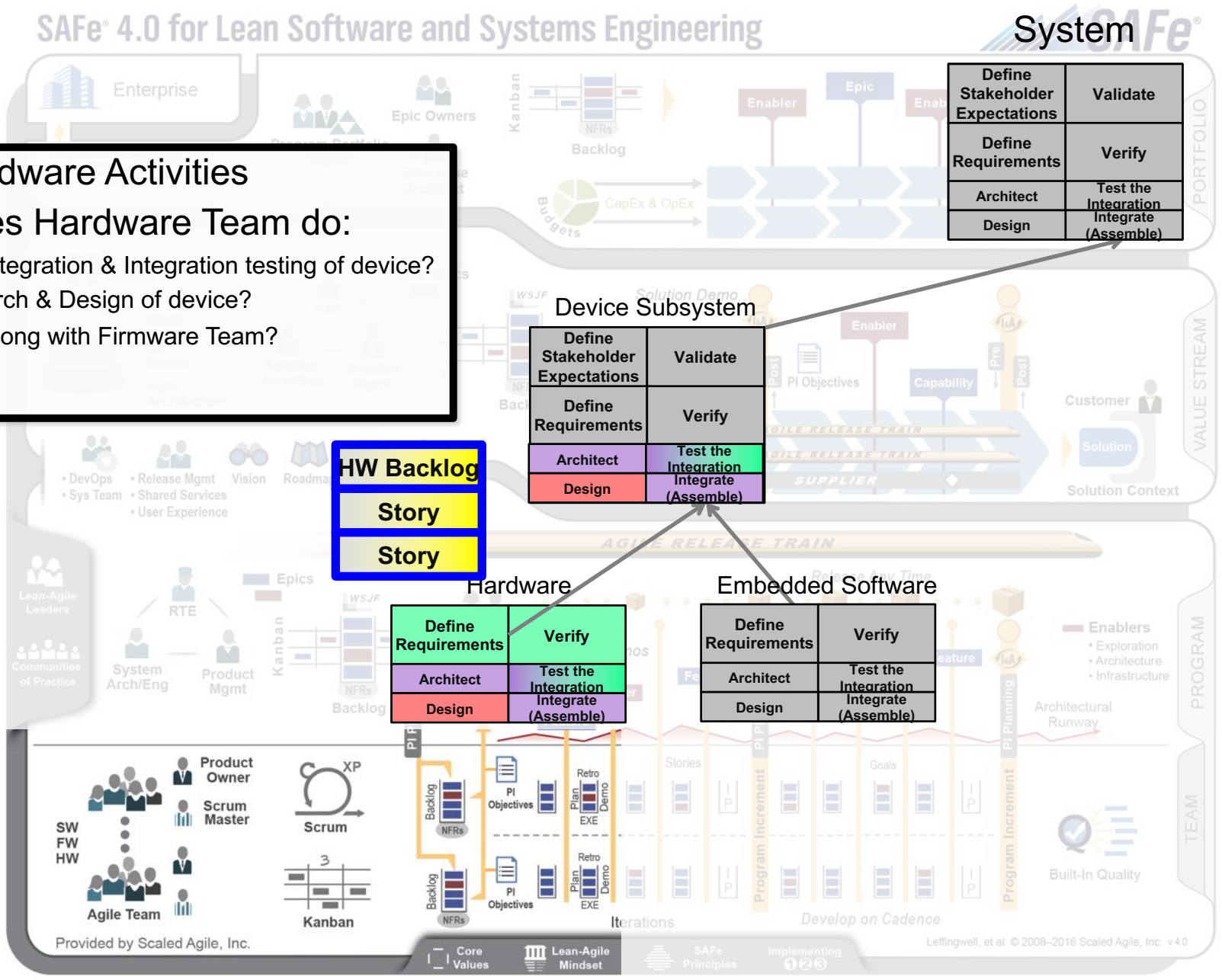
- Embedded SW Team does all activities for Embedded SW & Code
- Does team also do…?
  - Integration & Integration testing of device?
  - Arch & Design of device?



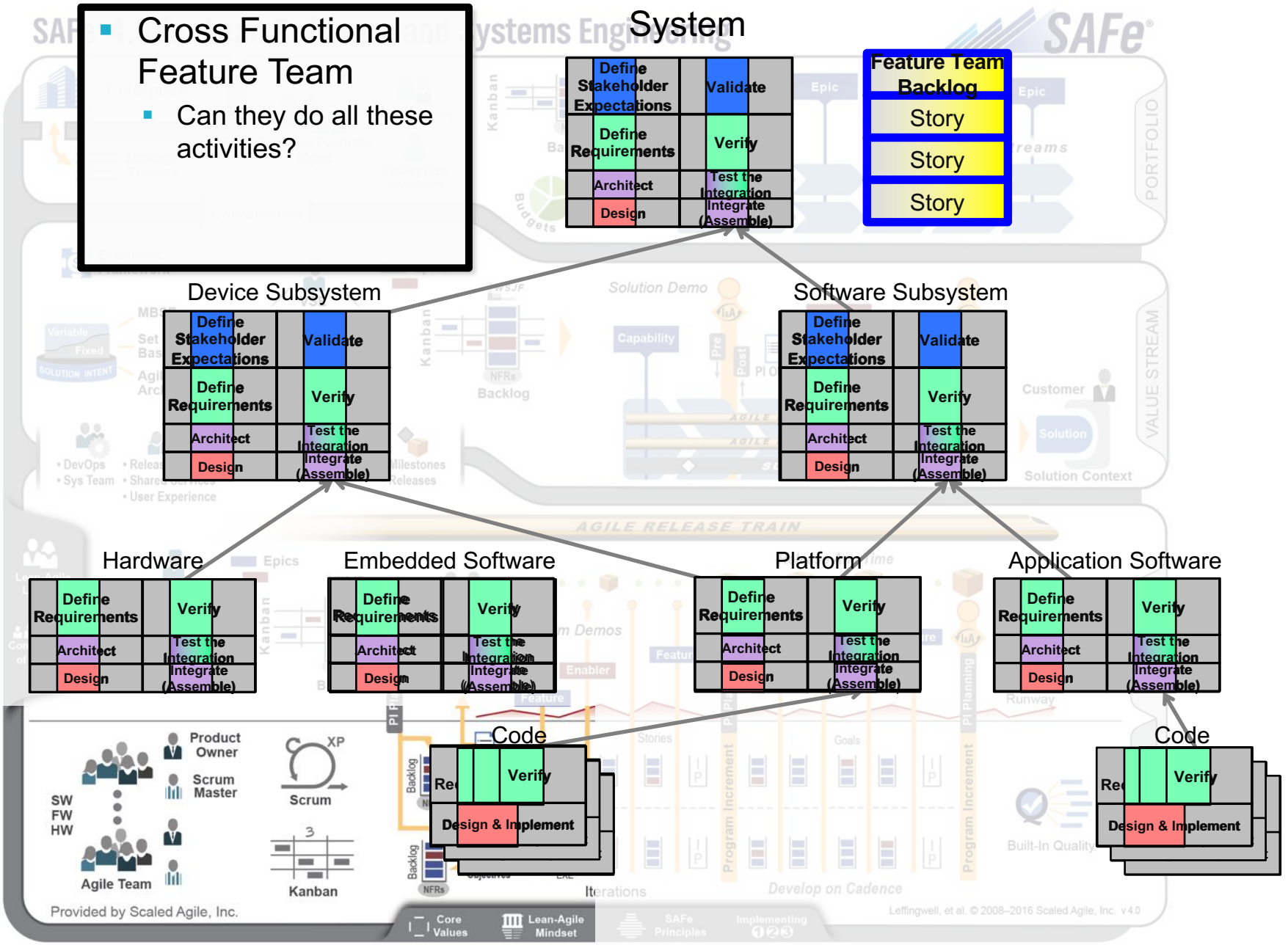
- FW Team's Backlog comes from:
  - System Requirements
  - Device Subsystem Stakeholder Expectations & Requirements
  - Application Software Requirements

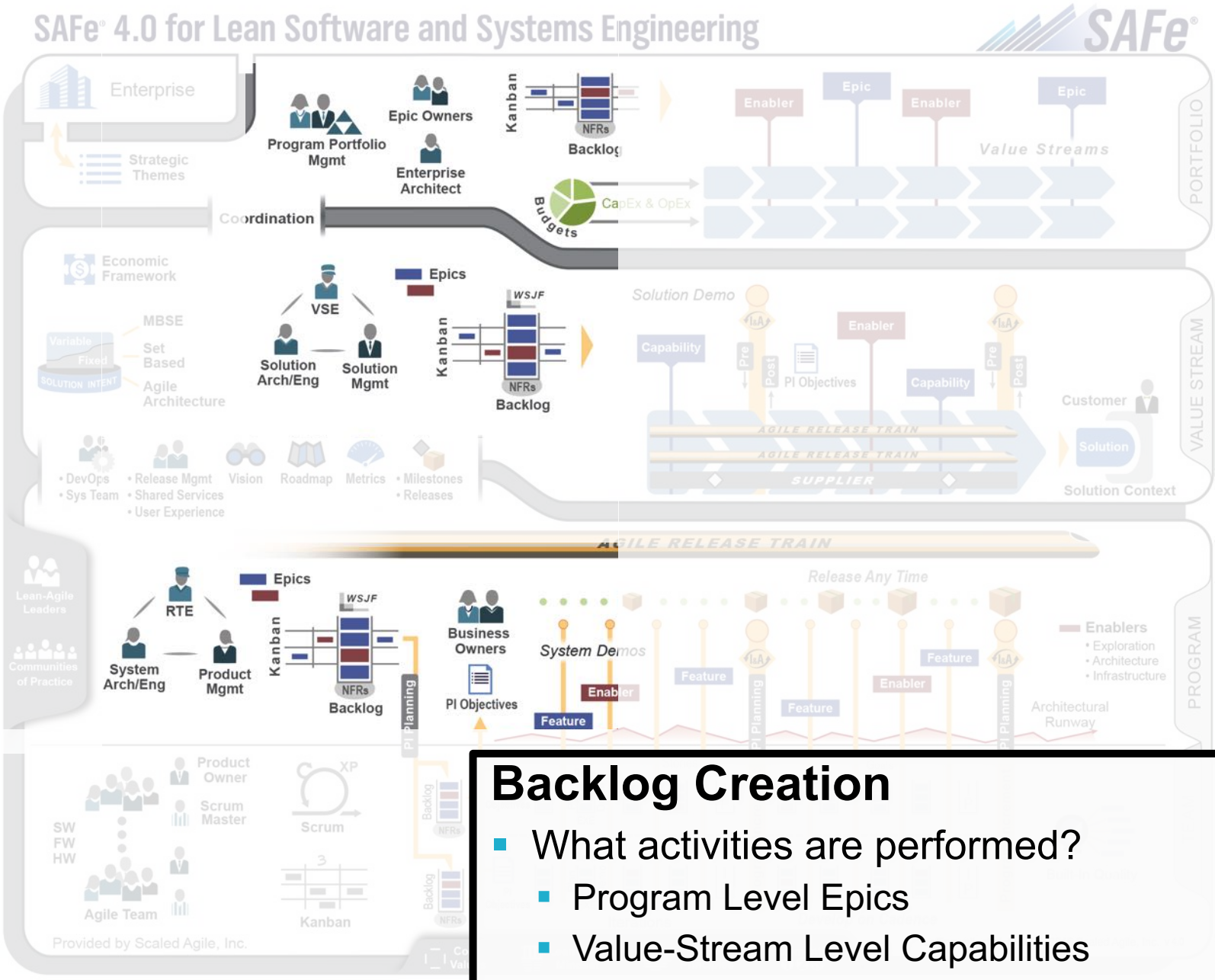


- Hardware Activities
- Does Hardware Team do:
  - Integration & Integration testing of device?
  - Arch & Design of device?
  - Along with Firmware Team?



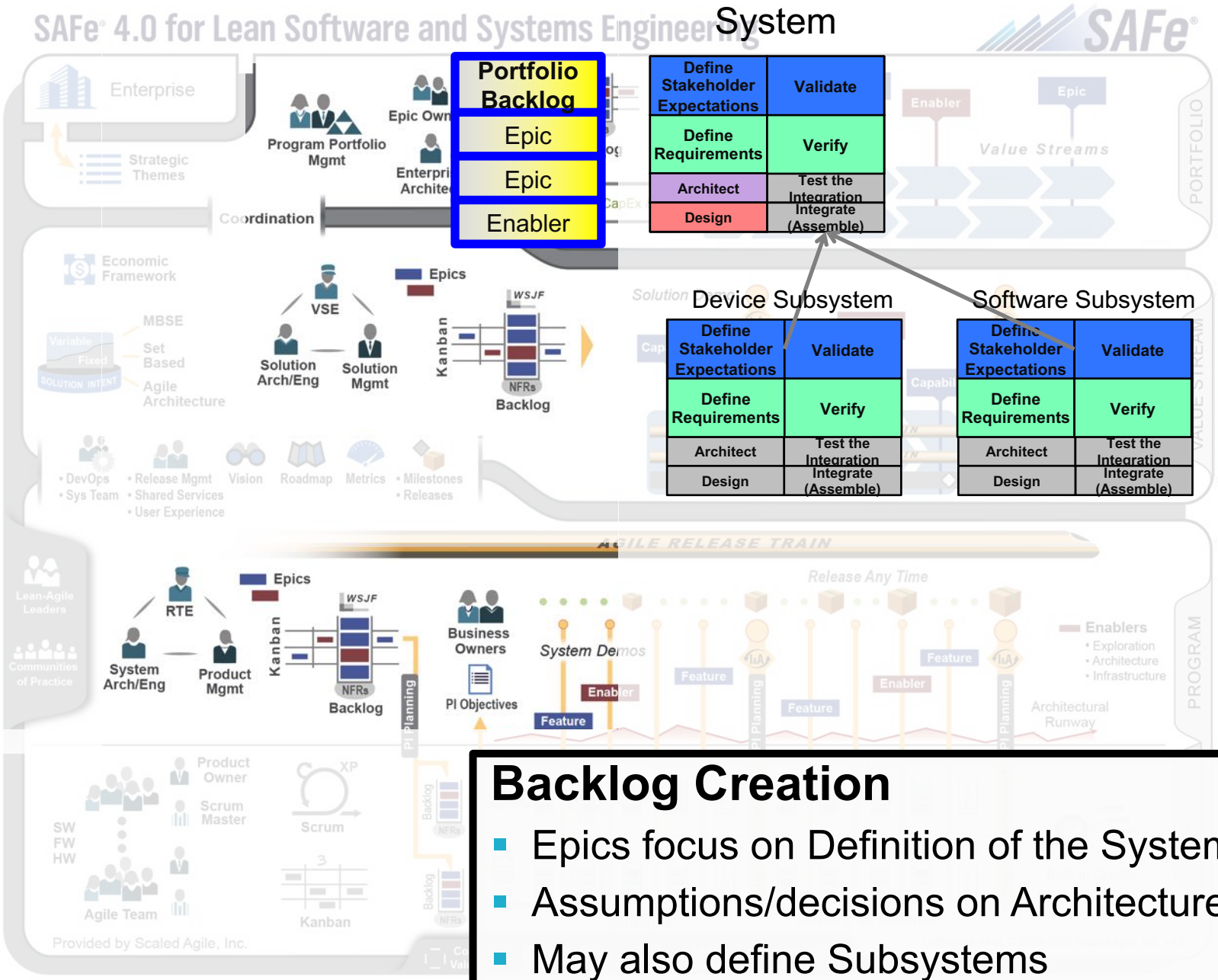
- Cross Functional Feature Team
  - Can they do all these activities?





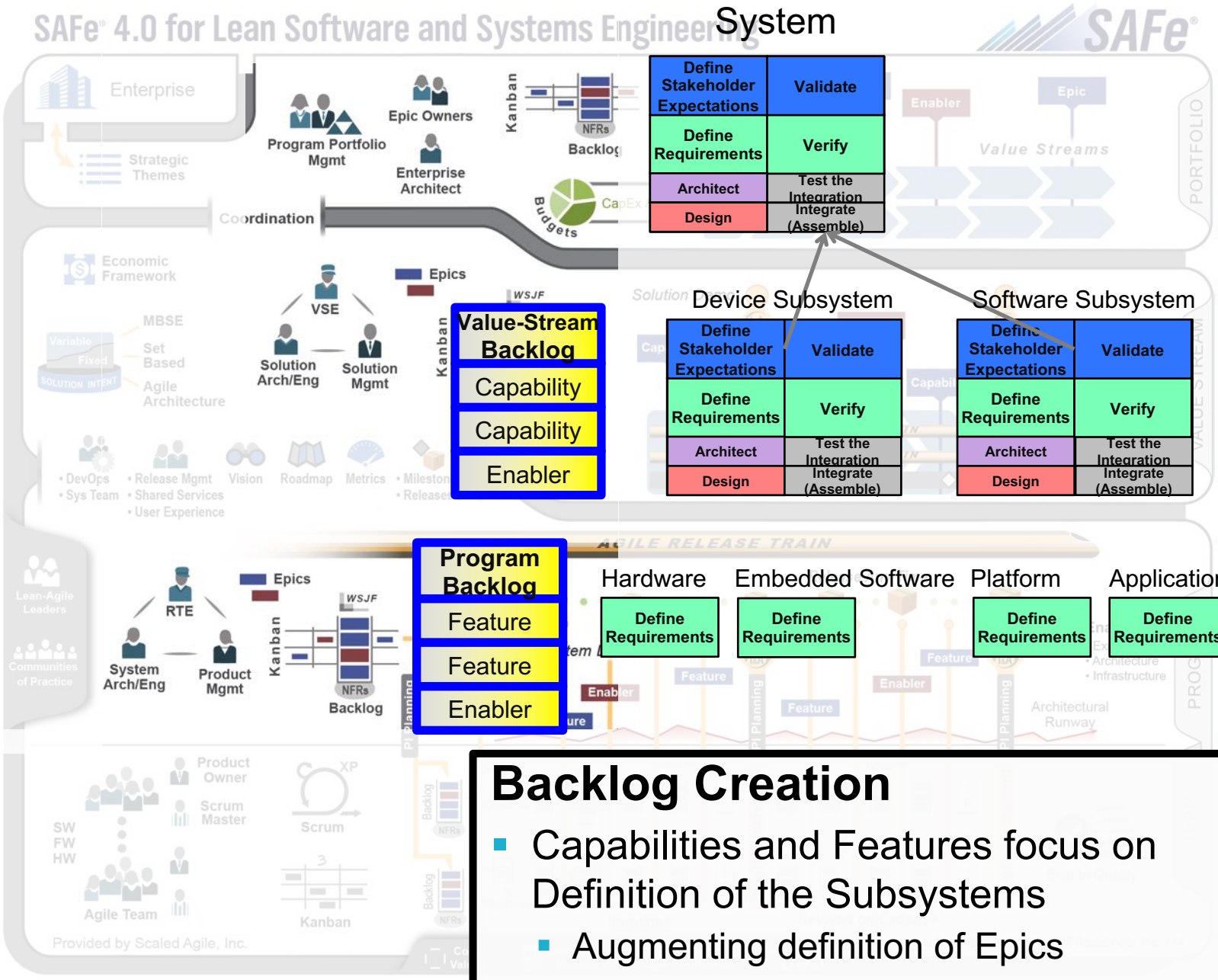
Backlog Creation

- What activities are performed?
  - Program Level Epics
  - Value-Stream Level Capabilities
  - Program Level Features



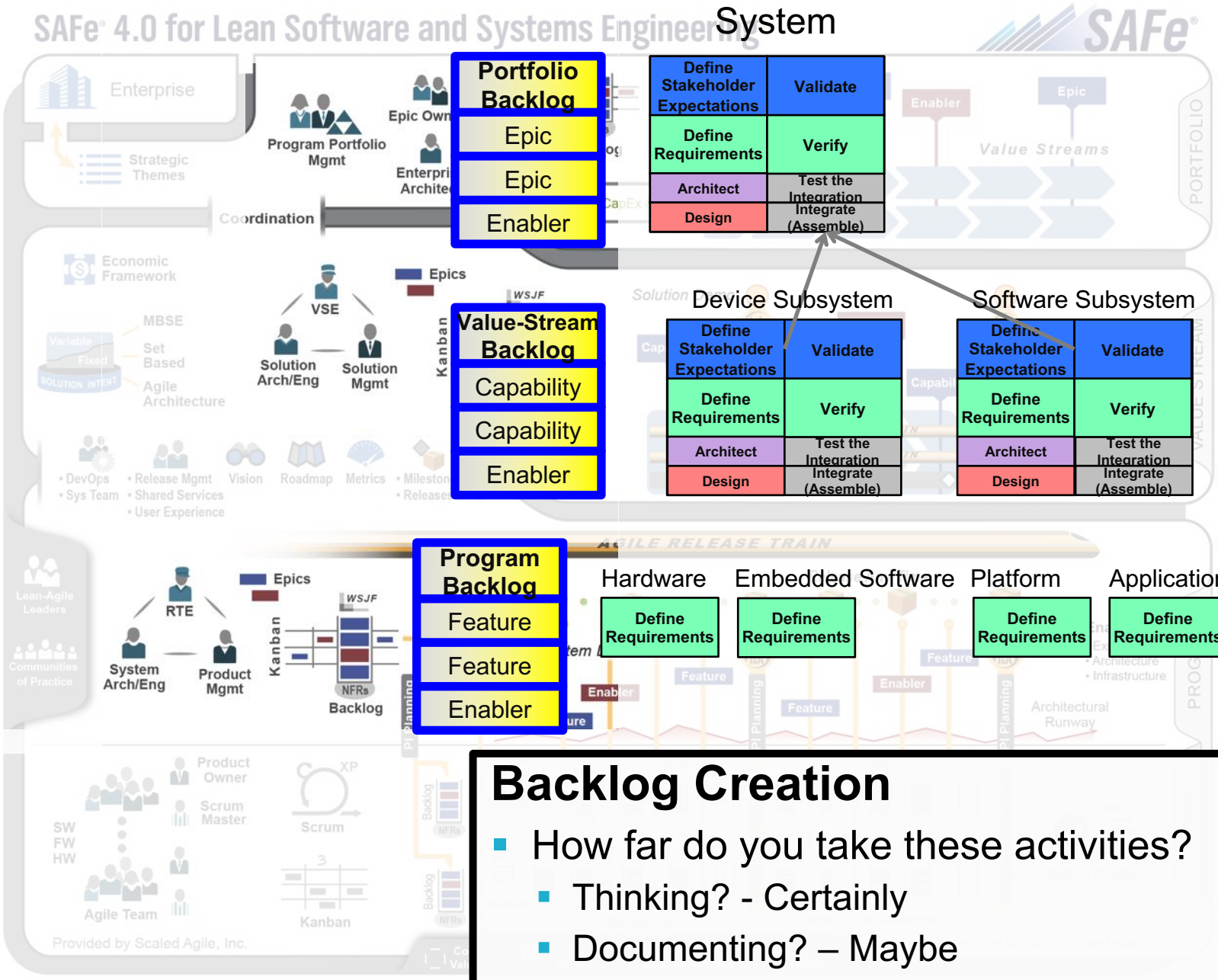
Backlog Creation

- Epics focus on Definition of the System
- Assumptions/decisions on Architecture
- May also define Subsystems



Backlog Creation

- Capabilities and Features focus on Definition of the Subsystems
  - Augmenting definition of Epics
  - May get into next-level arch & definition



Backlog Creation

- How far do you take these activities?
  - Thinking? - Certainly
  - Documenting? – Maybe
  - Formalizing? – Probably not

Where are the ARTs?

Applying SAFe® to the Development of a System

- What is the System?
- What is the Value Stream(s)?
- What is the ART(s)?

What is Your System?

System

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

Device Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
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Software Subsystem

Define Stakeholder Expectations	Validate
Define Requirements	Verify
Architect	Test the Integration
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Hardware

Define Requirements	Verify
Architect	Test the Integration
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Embedded Software

Define Requirements	Verify
Architect	Test the Integration
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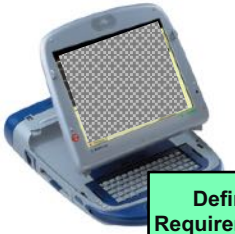
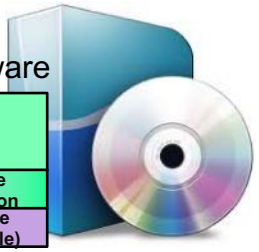


Platform

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)



Application Software

Define Requirements	Verify
Architect	Test the Integration
Design	Integrate (Assemble)

Code

Requ	Verify
Design & Implement	

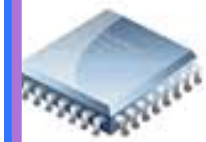
Code

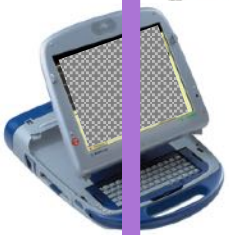
Requ	Verify
Design & Implement	

What is Your System?

Value Stream
One ART?

Subsystem = ART?





Subsystem = ART?

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