

# Functional Safety Management (FSM) for Managers...

Instrumentation Experts Club  
Automation India Week 2018

Sudhir Pai

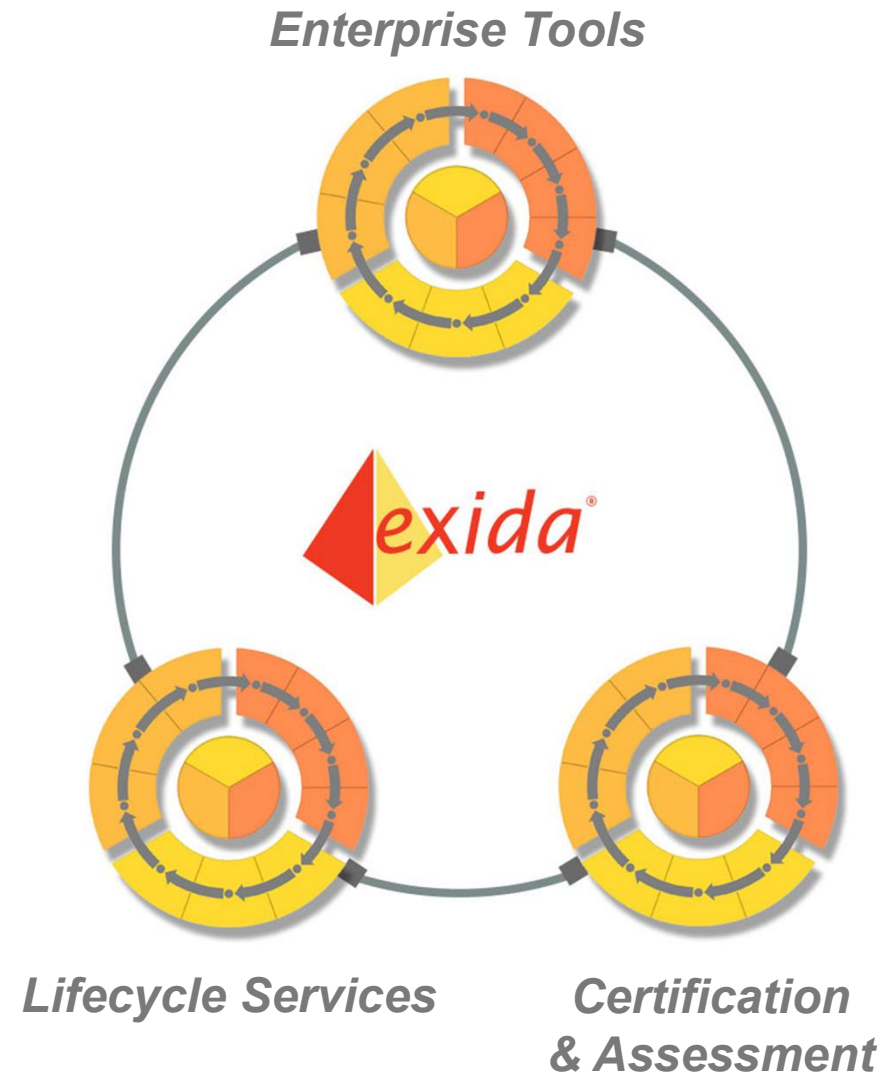
# exida... A Customer Focused Company

exida helps customers achieve safe and reliable solutions through:

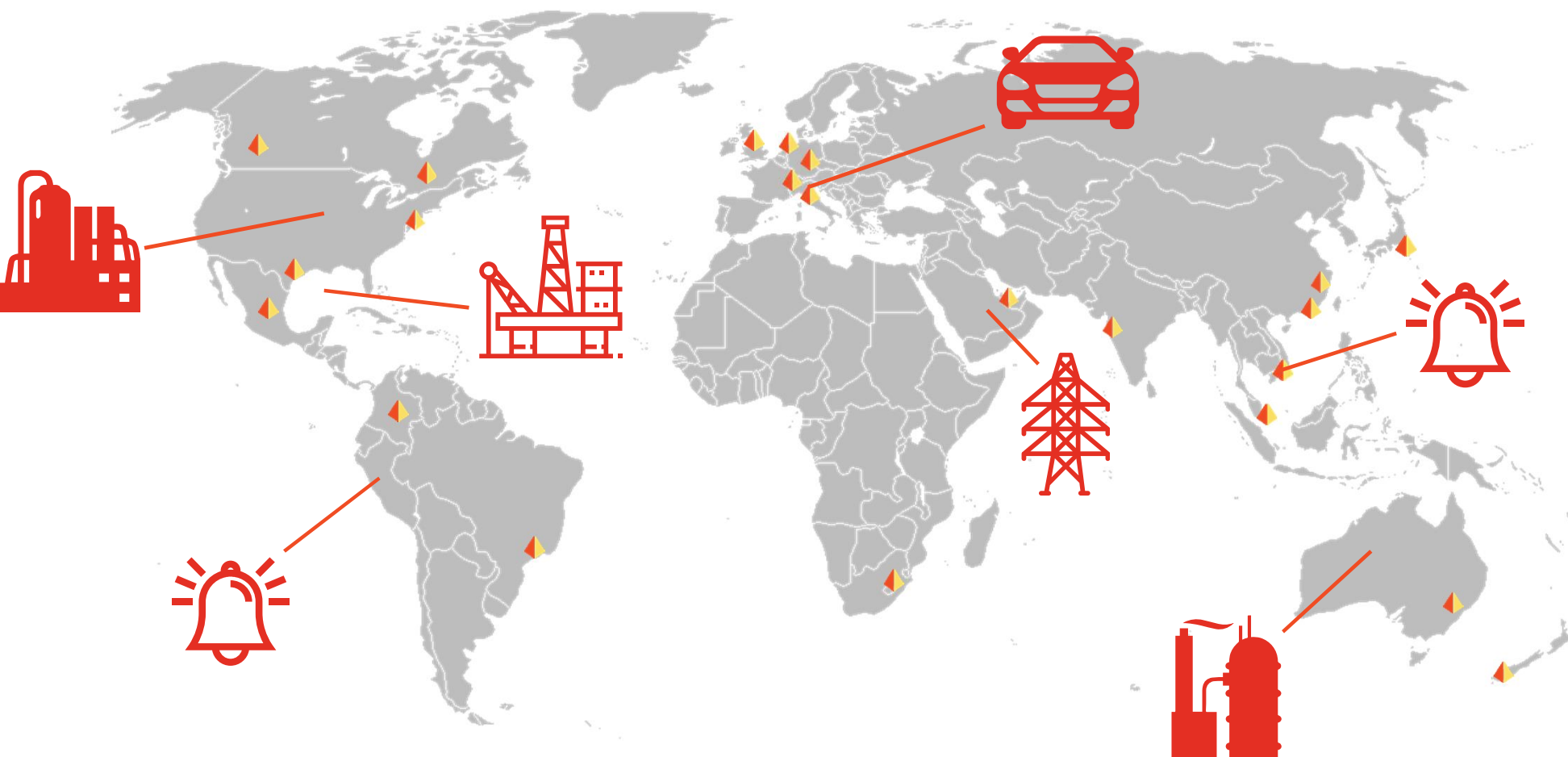
Powerful lifecycle tools that efficiently deliver technically correct results.

Thorough certification and assessment schemes that achieve compliance through a pragmatic approach.

Comprehensive lifecycle services that deploy experts to solve your toughest problems.



# *exida...* Global Customer Focus



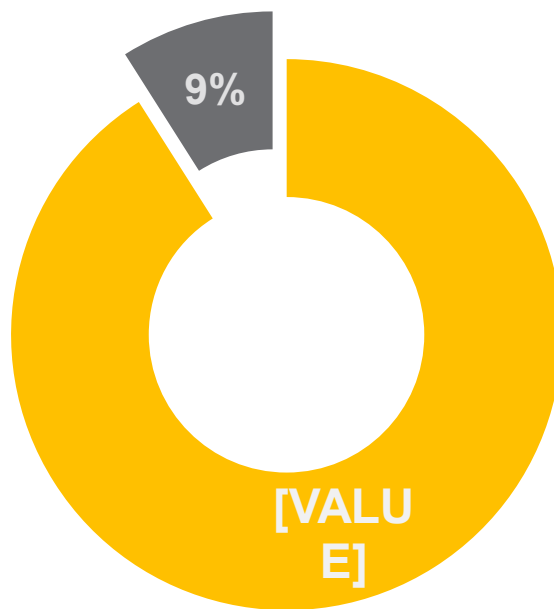
# How do We Measure Success?

## Market Share



Services cert\_exida   ■ Safety\_device cert\_TUV

Source: ARC Advisory Group, Nov. 2015

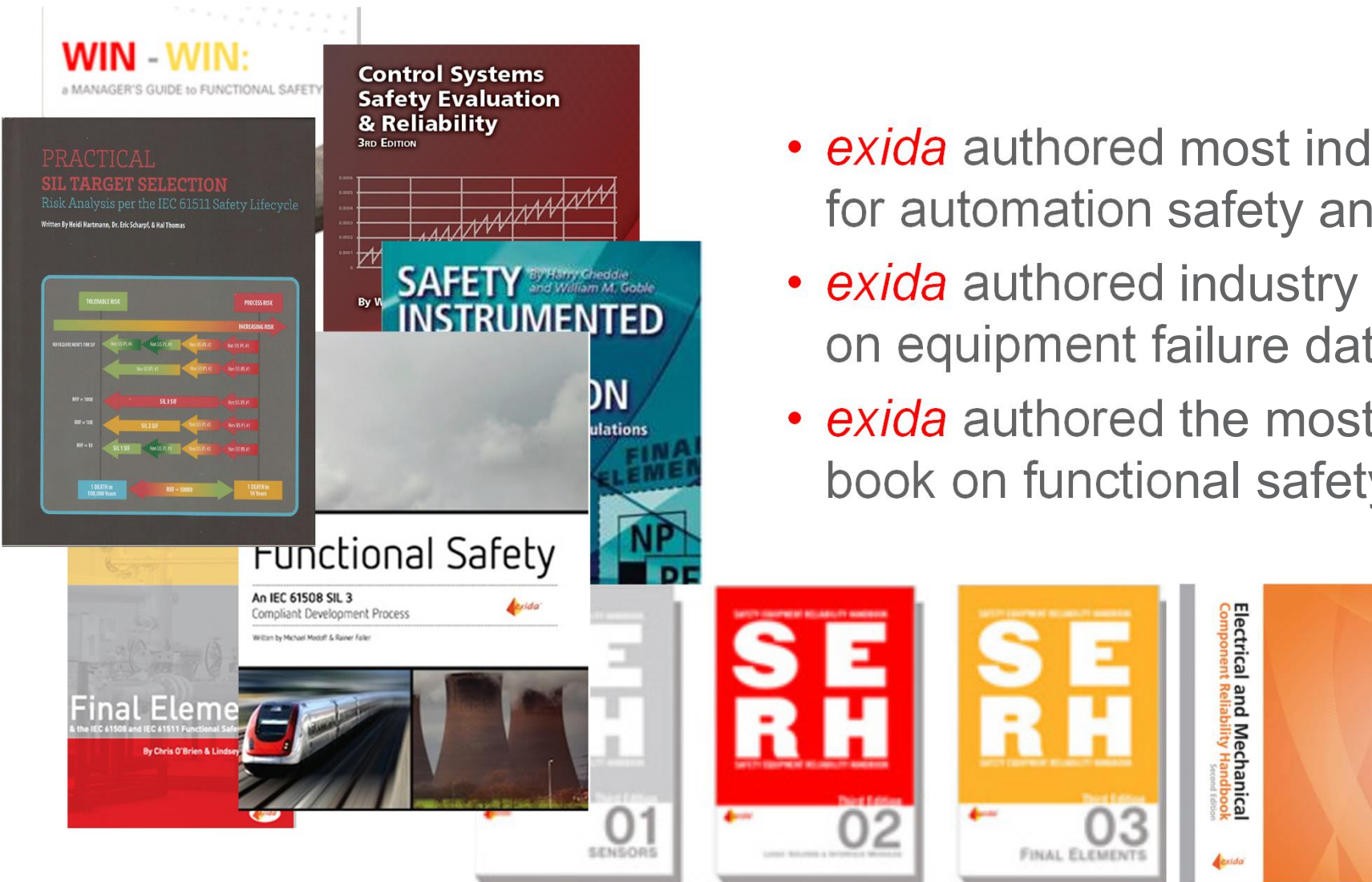


## Employee Ownership

## Key Statistics

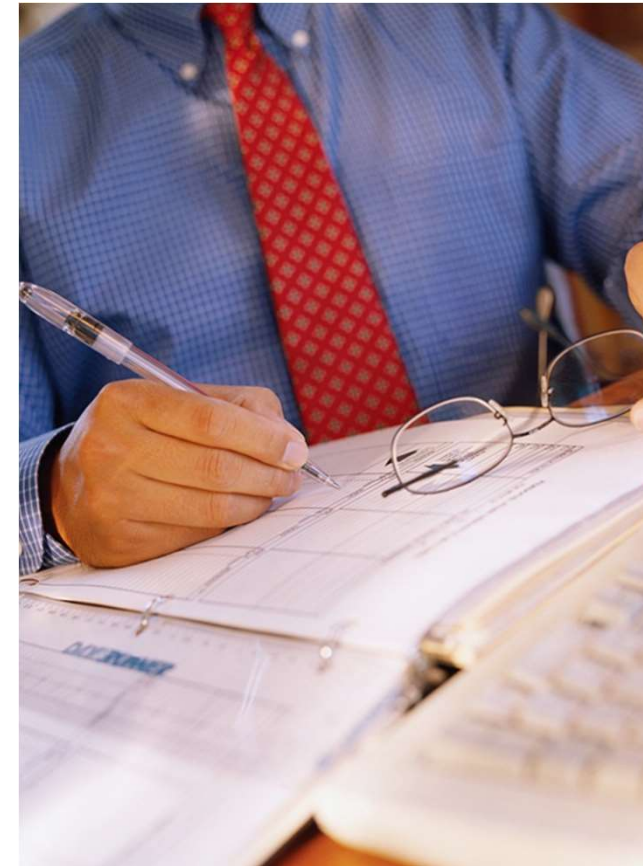
- Over 100 Global Experiences
- Over 1000 Certification and Assessment Projects
- Over 500,000 SIFs Modeled

# Reference Materials



- *exida* authored most industry reference materials for automation safety and reliability
- *exida* authored industry data handbooks on equipment failure data
- *exida* authored the most comprehensive book on functional safety in the market

# FUNCTIONAL SAFETY MANAGEMENT (FSM) FOR MANAGERS





# Introduction

Recent accidents have revealed deficiencies in Process Safety Management

- Poor safety culture
- Lack of mechanical integrity
- Poor maintenance & training

Management of Functional Safety is key to:

- Avoid and prevent systematic faults occurring
- Maintaining process safety
- Ensuring the integrity of SIS implementation



*BP Texas City Refinery Explosion 2005*

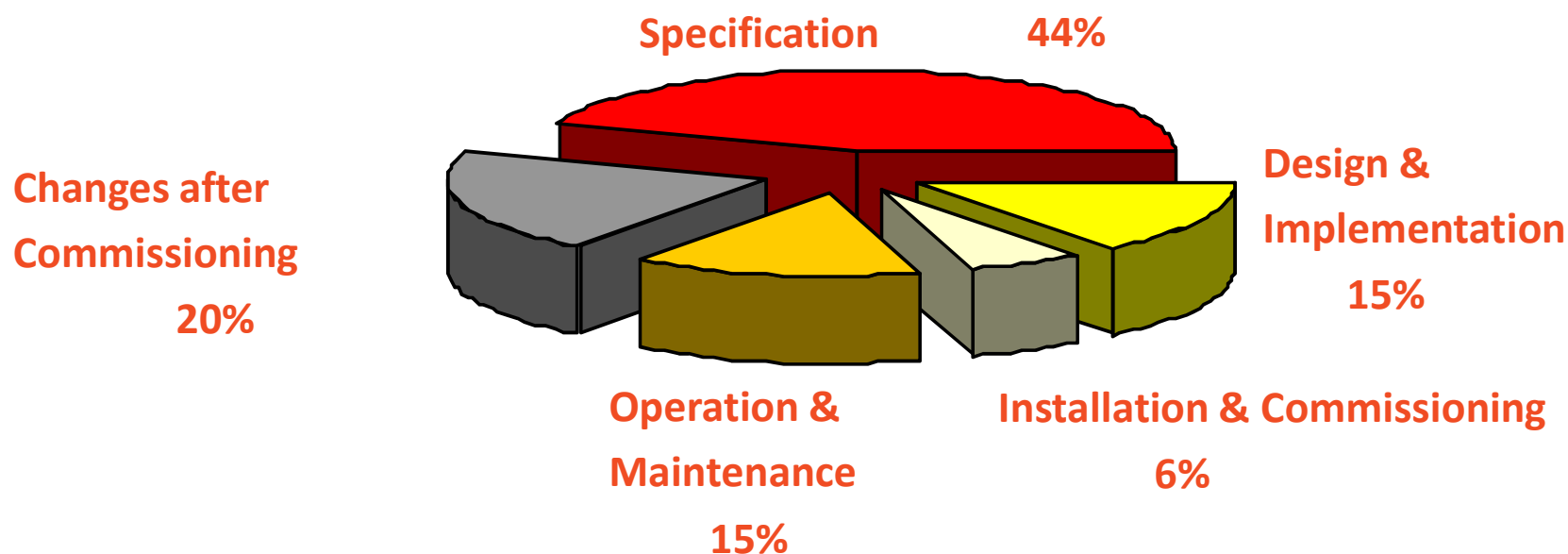
# Industrial Accidents

Incident	Country	Year	Fatalities	Injuries	Financial Impact
Exxon Valdez Oil Spill	USA	2010	11		Overall estimate >50 Billion; BP may have to pay the entire \$42 Billion cleanup bill, BP has estimated maximum possible fines could \$20 Billion if gross negligence is demonstrated. BP has paid out \$7 Billion in claims, further claims estimated at 15 Billion
San Bruno Pipeline Explosion	USA	2010	8	Many	Pacific Gas & Electric Co. has agreed to pay \$70 Million to aid city of San Bruno's recovery
Valdez Alaska Pipeline Spill	USA	2010			\$45 Million in lost production and about \$13 Million in state revenue
Marathon Oil Refinery	Venezuela	2012	48	151	Property Damage estimated at \$330 Million
East Fertilizer Company	USA	2013	15	260	Widespread community damage. Losses from the explosion are estimated to be around \$230 million + federal disaster assistance is estimated to exceed \$16 million
Wanxiang of Tanjin	China	2015	173	797	Cost to businesses estimated at \$9 billion; Various courts in China handed jail sentences to 49 government officials and company staff with a death sentence to Company chairman
Shell's Litvinov	Czech Republic	2015			Over 10 months of production loss. Cost of repair stands at almost €152 Million and lost business profit at over €244 Million.
		2018	6		Another incident with 6 deaths happened in 2018
Exxon oil refinery	USA	2018		36	Refinery isn't expected to reopen for at least 18 months. The fire and explosion resulted in \$27 million in damages and another \$53 million in unspecified costs related to the incident



# Industrial Accident Primary Causes

HSE study of accident causes involving control systems:



*"Out of Control: Why Control Systems go Wrong and How to Prevent Failure," U.K.:  
Sheffield, Health and Safety Executive, 1995 (Ed 2, 2003)*



**FOLLOWING BEST PRACTICE**

**FUNDAMENTAL FUNCTIONAL SAFETY  
REQUIREMENTS**

# What is Risk?

Risk is a measure of the  
**LIKELIHOOD** and  
**CONSEQUENCE**  
of an adverse effect  
*(i.e., How often can it happen and  
what will be the effects if it does?)*

- Risk receptors:
  - Personnel
  - Environment
  - Financial
  - Equipment/Property Damage
  - Business Interruption
  - Business Liability
  - Company Image
  - Lost Market Share

# What is Functional Safety?

Functional Safety” is a set of rules and methods for the specification, design, and operation of safety functions which are part of **Automatic Protection Systems.**

# Following Best Practice

COMAH/OSHA CFR1910 requires operators of hazardous processes to follow best practice

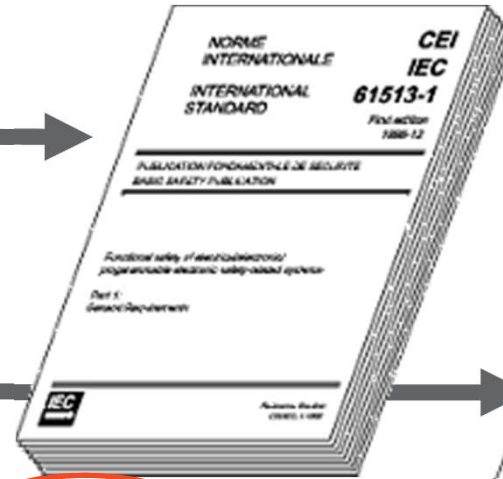
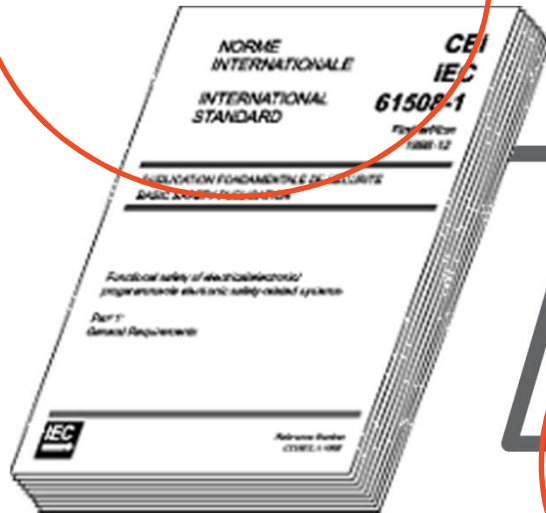
IEC61511/S-84 is recognized as being RAGAGEP (Recognized and Generally Accepted Good Engineering Practice)

IEC61511 is a **performance-based standard** built around a Safety Lifecycle (SLC) to

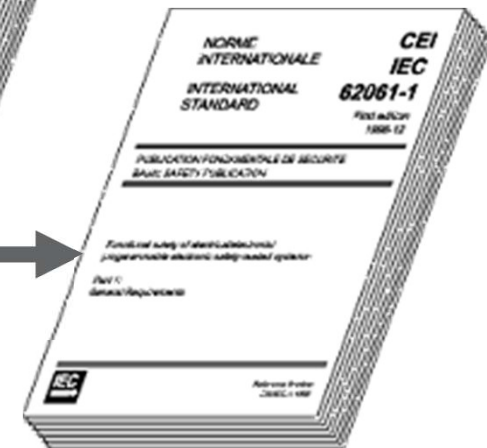
- Ensure the problems of the past are not repeated
- Provide a consistent approach to identifying and mitigating risk
- Provide a means of achieving optimum design that balances risk reduction with performance
- Provide a means to consistently measure performance

# Current Functional Safety Standards

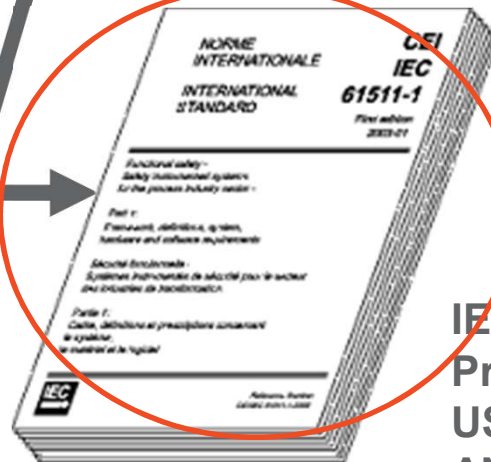
**IEC 61508**  
International Performance  
Based Standard for all  
Industries



**IEC 61513**  
Nuclear  
Sector



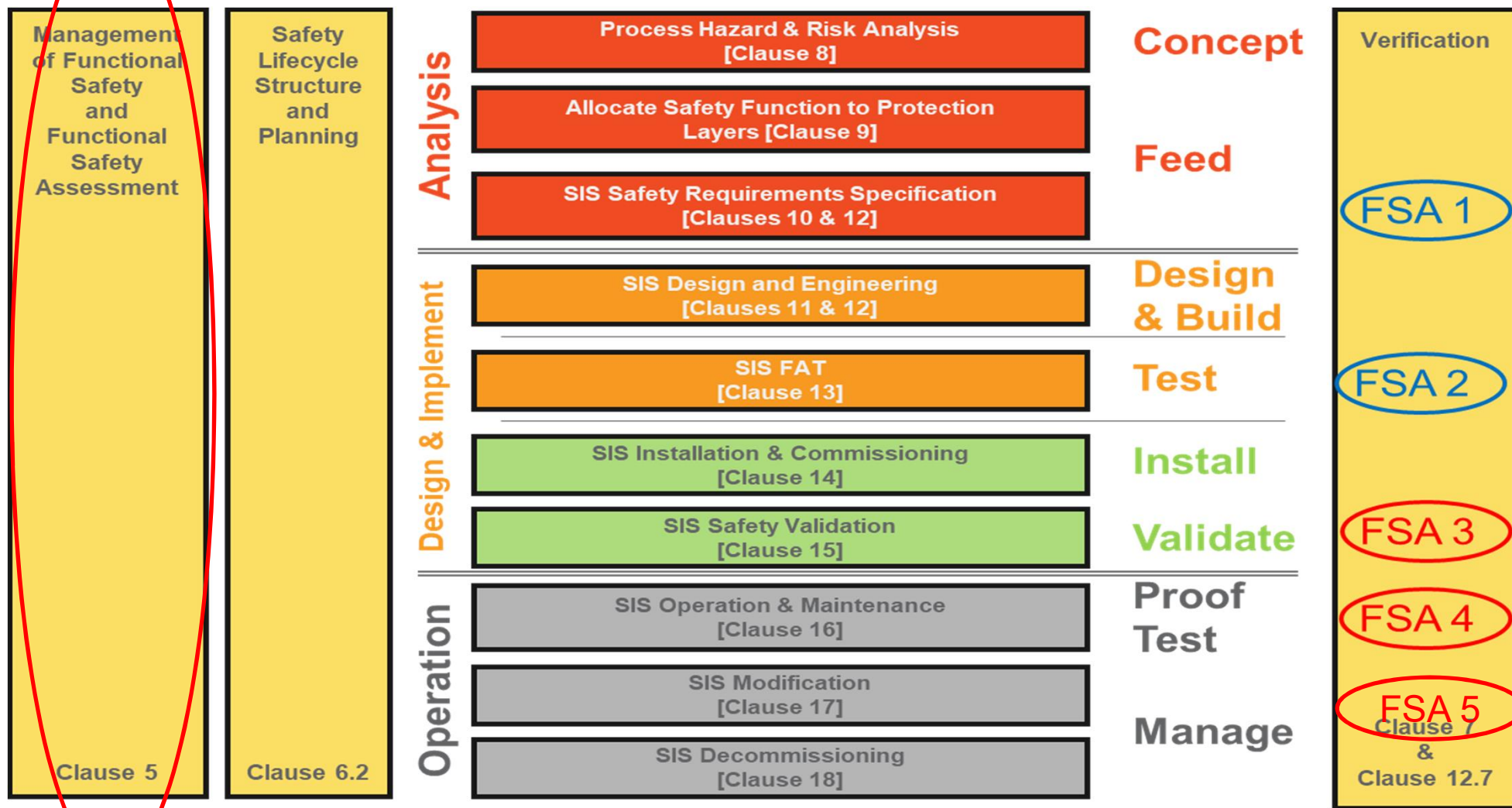
**IEC 62061**  
Machinery Sector



**IEC 61511**  
Process Industry Sector  
USA uses  
ANSI/ISA-84.00.01-2004 (IEC 61511 Mod)

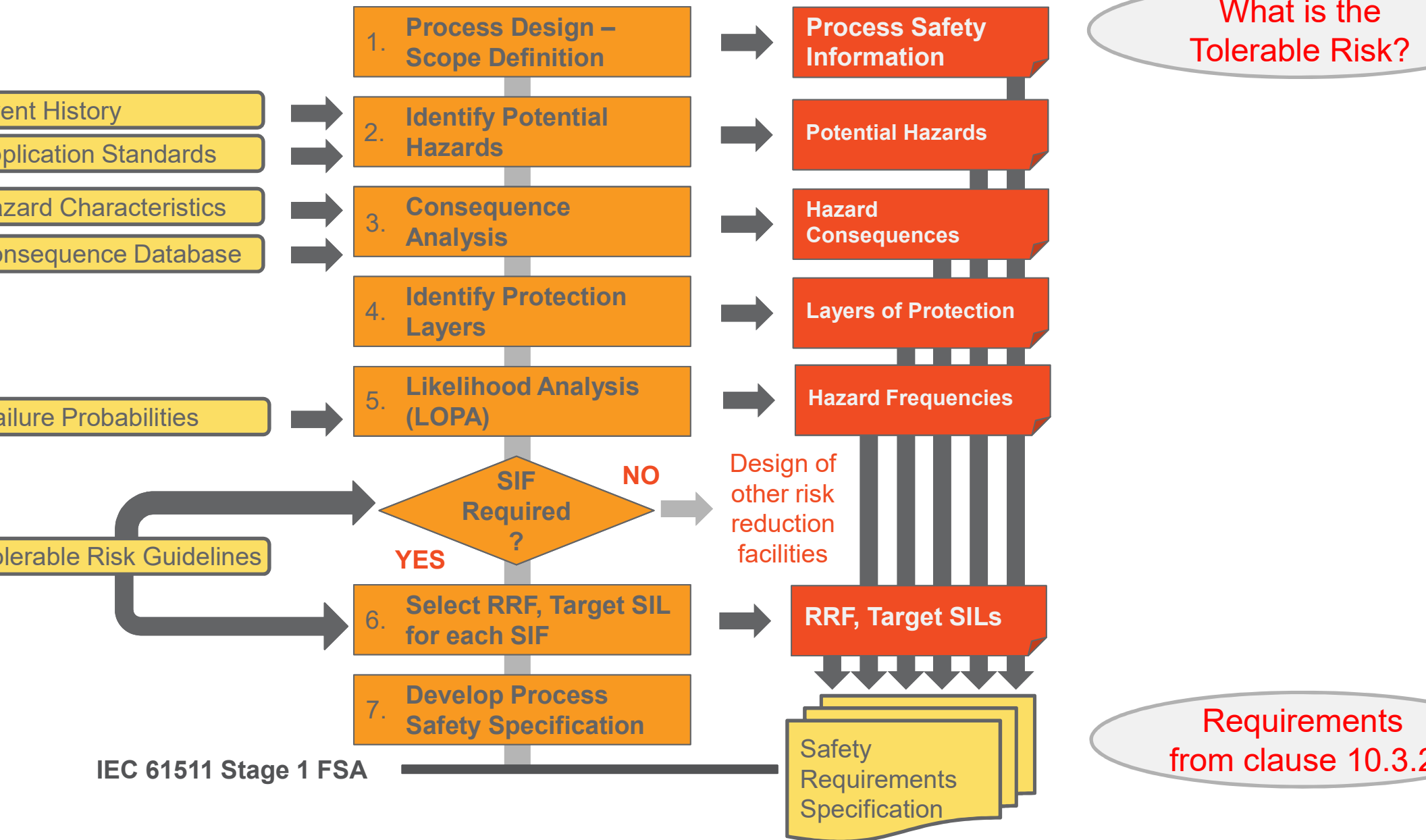
**Sector Standard**

# IEC 61511 Safety Lifecycle

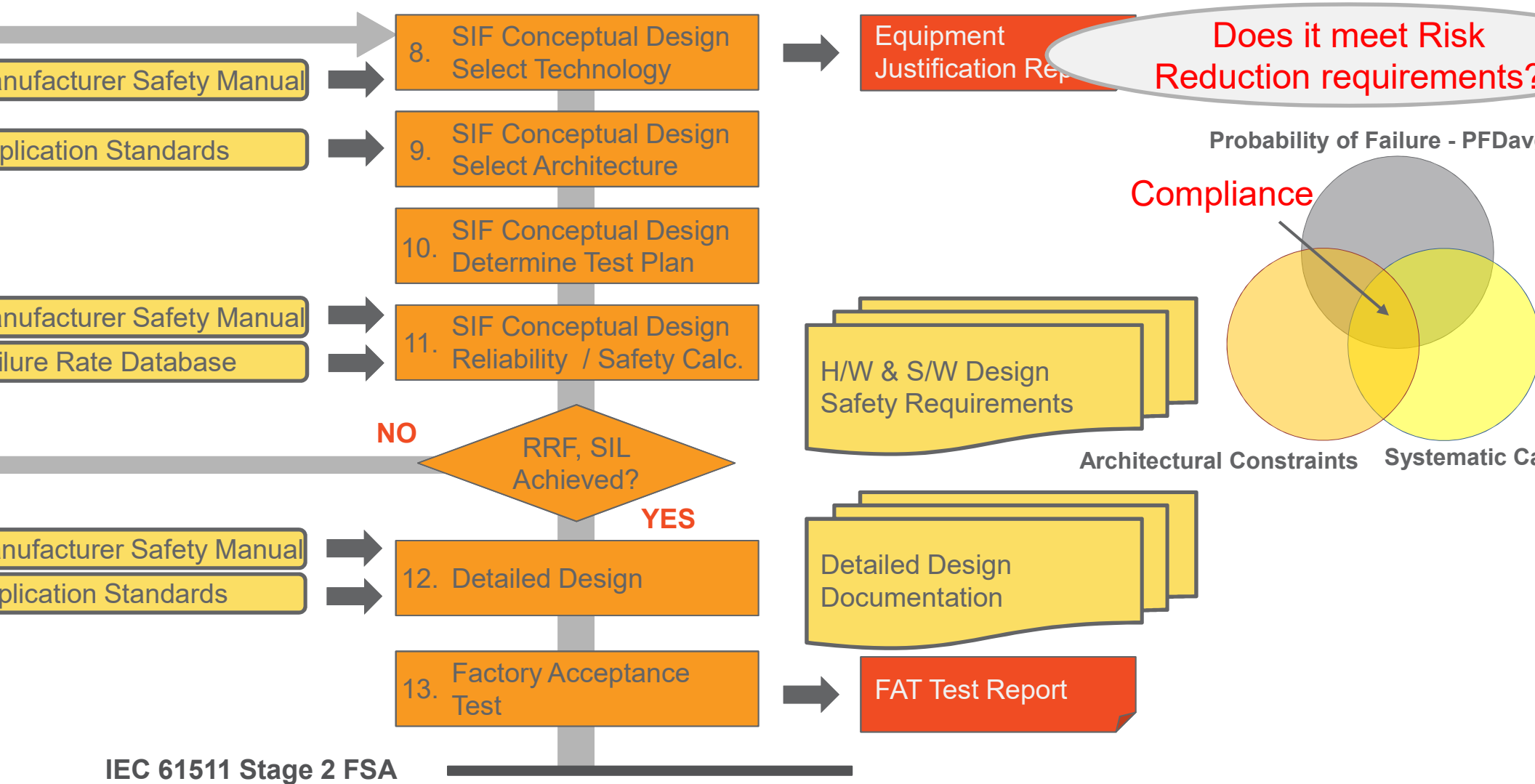




# "Analysis" Information Flow



# "Realization" Information Flow



# Manufacturer's Certificates

Manufacturer's IEC 61508 functional safety certificates should provide key pieces of information:

1. Systematic Capability
2. Failure Rate Data
3. Architecture Constraint Type
4. Statement of Compliance
5. Accreditation Body

**Certificate / Certificat / Zertifikat / 合格証**

HON 1002038 C001  
exida hereby confirms that the:

**SmartLine ST 800 HART  
Pressure Transmitter**

**Honeywell International Inc.  
Honeywell Field Products  
Fort Washington, PA 19034 - USA**

Has been assessed per the relevant requirements of:

**IEC 61508 : 2010 Parts 1-7**

and meets requirements providing a level of integrity for:

**Systematic Capability: SC 3 (SIL 3 Capable)**

**Random Capability: Type B Element**

**SIL 2 @ HFT=0; SIL 3 @ HFT = 1; Route 2<sub>H</sub>**

**PFD<sub>avg</sub> and Architecture Constraints must be verified for each application**

**Safety Function:**  
The ST 800 HART Pressure Transmitter with 4-20 mA 2-wire interface will measure pressure within the stated safety accuracy.

**Application Restrictions:**  
The unit must be properly designed into a Safety Instrumented Function per the Safety Manual requirements.

**ANSI**  
Accredited Program  
FUNCTIONAL SAFETY CERTIFICATION  
#1004

**John C. Yozellinas**  
Evaluating Assessor

**Phil K...**  
Certifying Assessor

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**Certificate / Certificat / Zertifikat / 合格証**

HON 1002038 C001

**Systematic Capability: SC 3 (SIL 3 Capable)**

**Random Capability: Type B Element**

**SIL 2 @ HFT=0; SIL 3 @ HFT = 1; Route 2<sub>H</sub>**

**PFD<sub>avg</sub> and Architecture Constraints must be verified for each application**

**SmartLine ST 800 HART  
Pressure Transmitter with  
4-20 mA 2-wire interface**

**Systematic Capability:**  
The product has met manufacturer design process requirements of Safety Integrity Level (SIL) 3. These are intended to achieve sufficient integrity against systematic errors of design by the manufacturer.  
A Safety Instrumented Function (SIF) designed with this product must not be used at a SIL level higher than stated.

**Random Capability:**  
The SIL limit imposed by the Architectural Constraints must be met for each element. This device meets exida criteria for Route 2<sub>H</sub>.

**IEC 61508 Failure Rates in FIT\***

Device	$\lambda_{SD}$	$\lambda_{SU}$	$\lambda_{DD}$	$\lambda_{DU}$
ST 800 Pressure Transmitter HART with 4-20mA	0	40	364	42

\* FIT = failure / 10<sup>9</sup> hours

**SIL Verification:**  
The Safety Integrity Level (SIL) of an entire Safety Instrumented Function (SIF) must be verified via a calculation of PFD<sub>avg</sub> considering redundant architectures, proof test interval, proof test effectiveness, any automatic diagnostics, average repair time and the specific failure rates of all products included in the SIF. Each element must be checked to assure compliance with minimum hardware fault tolerance (HFT) requirements.

The following documents are a mandatory part of certification:  
**Assessment Report:** HON 10-02-038 R006 V1 R4  
**Safety Manual:** Doc # 34-ST-25-37

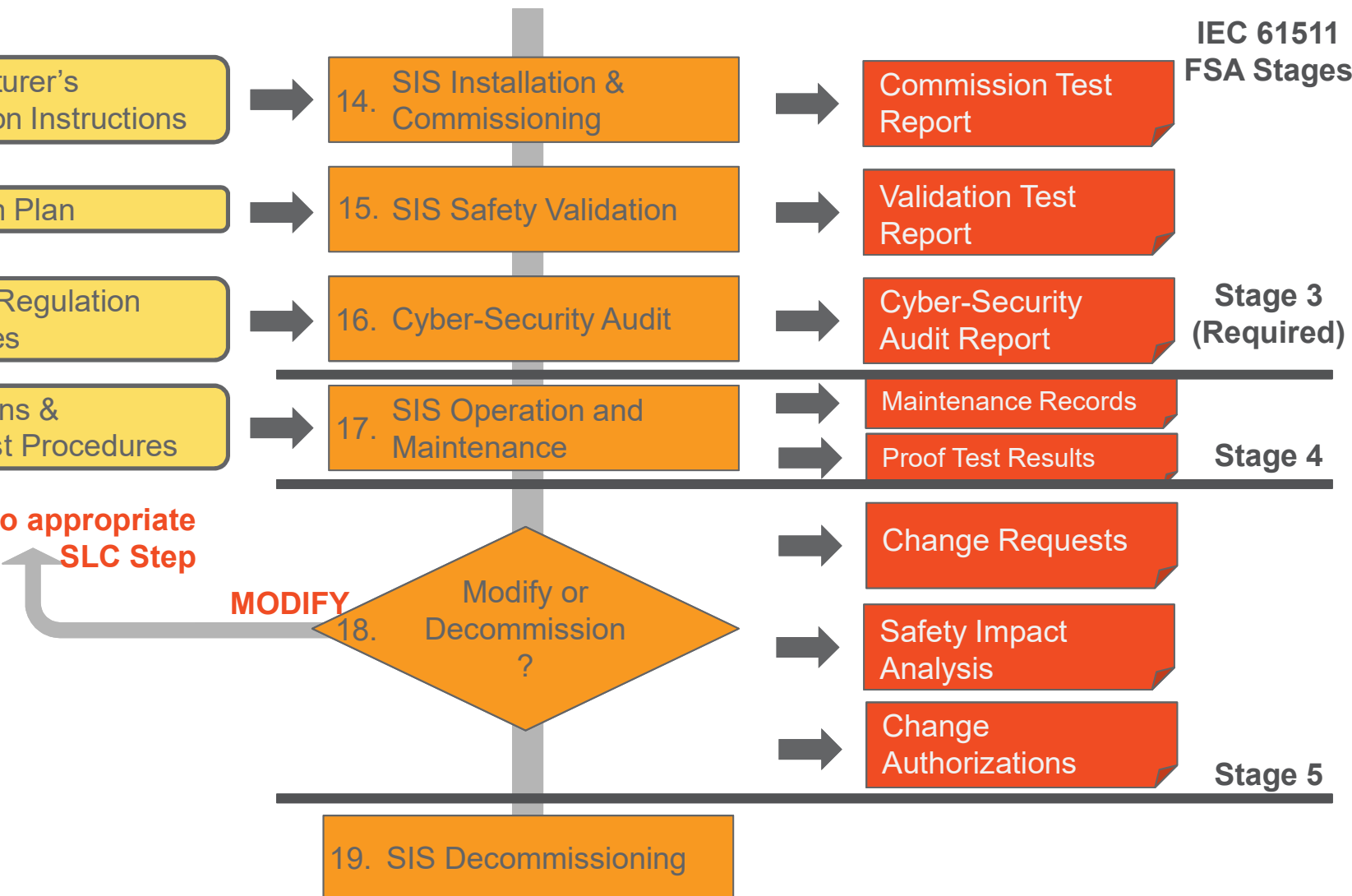
**exida**

80 N Main St  
 Sellersville, PA 18960

T-002, V3R10

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# “Operation” Phases Information Flow



- O&M planning
- Inspection & proof test planning / execution
- Equipment replacement
- *End of life refurbishment and replacement*
- **Failure event data collection**
- Functional safety process auditing
- Modification approval and validation

# IEC 61511 Now Includes Cyber Requirements for the SIS

The new version of IEC 61511 emphasizes the need for Cyber Assessment (Clause 8.2.4):

- Security Risk Assessments including a description of identified threats, the likelihood and potential consequences of a security event.
- Determination of requirements for additional risk reduction.
- Description of measures taken to reduce or remove threats.

Emphasizes the responsibility of the owner / operating company of the of the facility (Clause 8.2.4, Note 2).

# Consequences of incomplete CSMS

**Iranian Nuclear Facility** - STUXNET – direct failure of a process equipment

**Yahoo** – 1 billion user accounts compromised

**LinkedIn** – 160 million accounts compromised

**Target, Sony, Home Depot** – retailers compromised

**Lockheed** – F035 fighter jet program

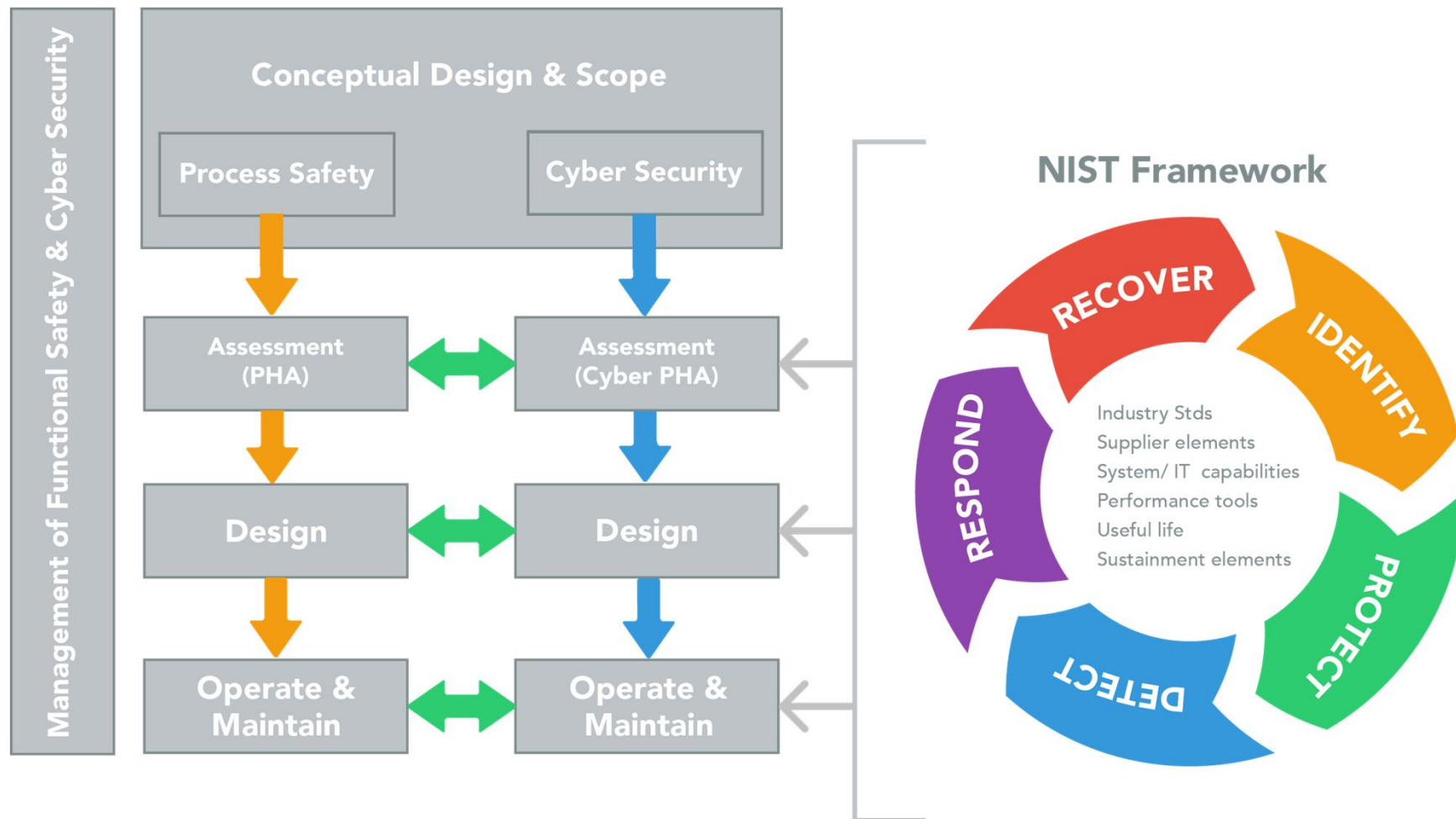
**German Steel Mill** – “spear phishing” success leads to attack on blast furnace control

**Ukrainian Power Grid** – “KillDisk” virus attack bricked switching station in 2015, second attack a year later

**National Laboratories** – disrupted communications

**Pentagon Files** – compromised file content not released

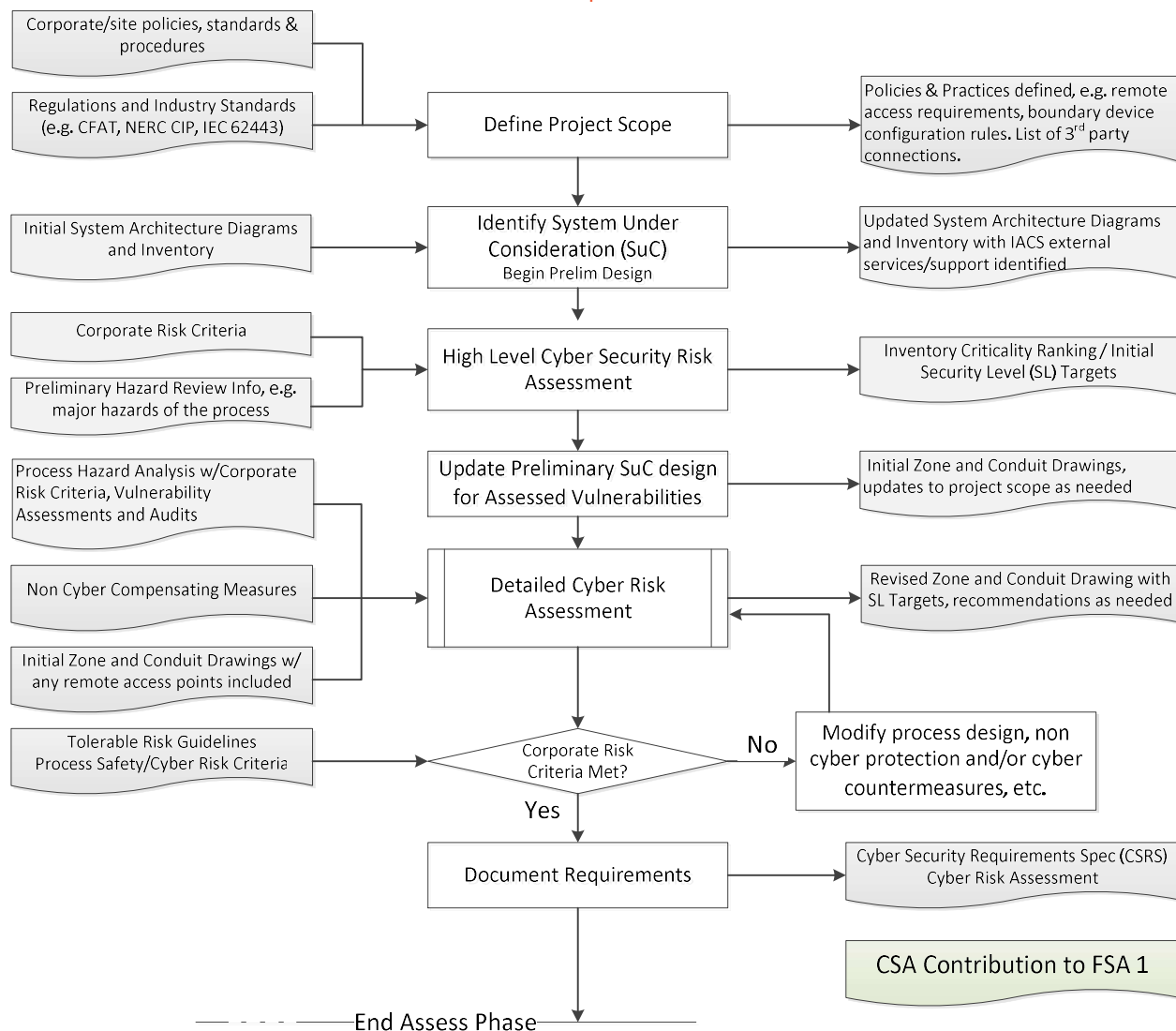
# Safety/Cybersecurity Integration





# Cybersecurity Assessment Phase

Excerpted from ISA TR84.00.09



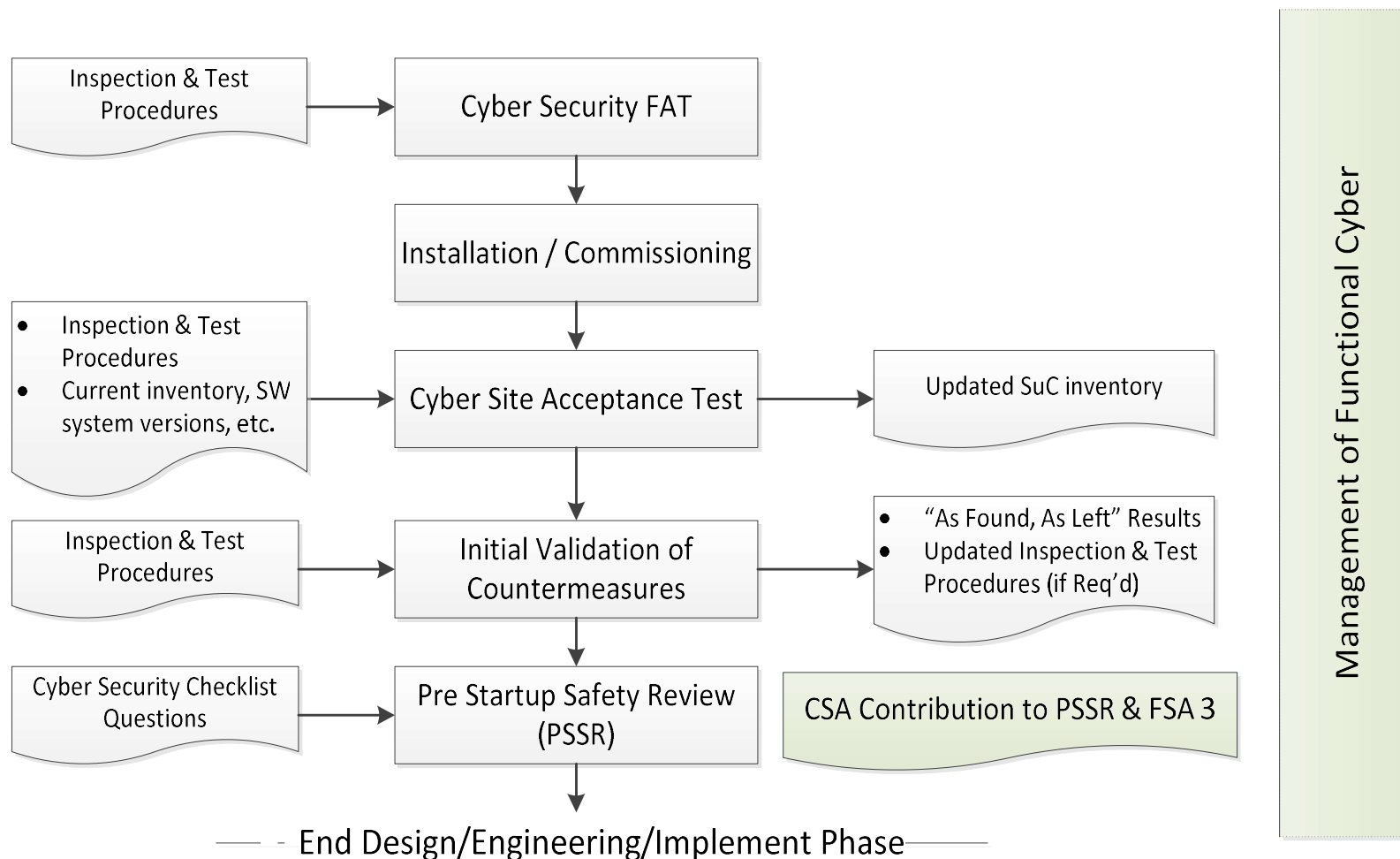
Management of Functional Cyber

Excerpted from ISA TR84.00.09

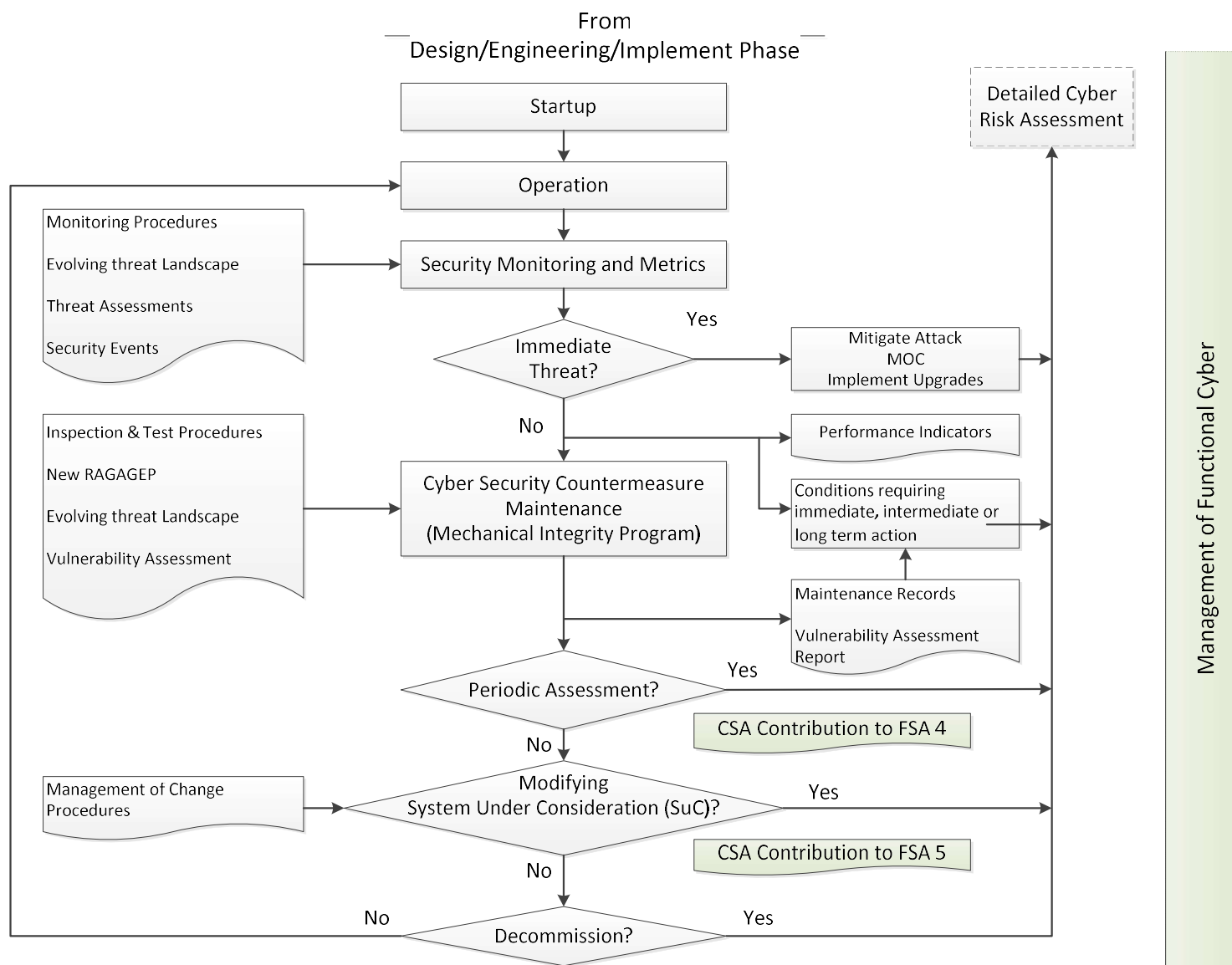


# Design & Implement(2)

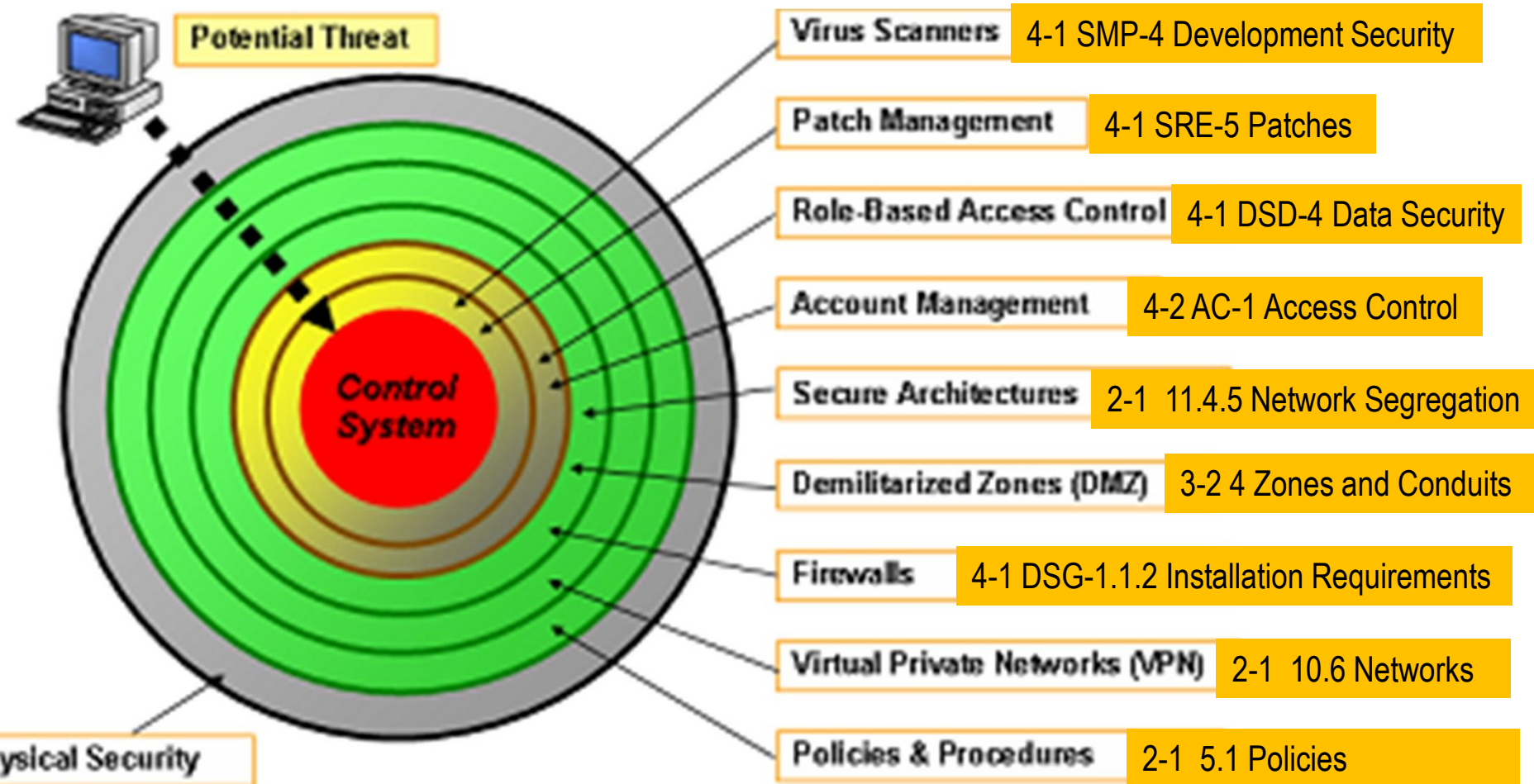
Excerpted from ISA TR84.00.09



# Operate & Maintain Excerpted from ISA TR84.00.09



# Defense In Depth



# IEC 62443 family of cyber standards

General	IEC 62443-1-1 Terminology, Concepts and Models	IEC 62443-1-2 Master Glossary of Terms and Abbreviations	IEC 62443-1-3 System security compliance metrics	
	IEC 62443-2-1 Establishing an IACS Security Program	IEC 62443-2-2 Operating an IACS Security Program	IEC 62443-2-3 Patch Management in the IACS Environment	IEC 62443-2-4 Security Program Requirements for IACS Service Providers
	IEC 62443-3-1 Security Technologies for IACS	IEC 62443-3-2 Security Assurance Levels for Zones and Conduits	IEC 62443-3-3 System Security Requirements and Security Assurance Levels	
	IEC 62443-4-1 Product Development Lifecycle Requirements	IEC 62443-4-2 Technical Security Requirements for IACS Components		

# Functional Safety Management

Functional Safety Management is about

- **People**
- **Procedures**
- **Paperwork**

← The 3 Ps!

Apply the same redundancy to these as for equipment to ensure systematic errors are:

- Rarely created
- Easily identified
- Promptly corrected



# Functional Safety Management

Governs the entire Safety Lifecycle

Allocating lifecycle responsibilities

Specifying the activities of those with responsibilities (develop procedures)

Ensuring people are competent



***Manage the risk of systematic faults to get an acceptable level of overall risk***

***So what does this mean for me as manager?***

# What Are Your Responsibilities?

Managers need to be able to demonstrate competence according to IEC61511:2016, in terms of having:

- knowledge of the legal and regulatory functional safety requirements
- understanding of the potential consequence of an event
- adequate management and leadership skills appropriate to their role in the SIS safety lifecycle activities

Managers need to read incident reports and to ensure leading and lagging indicators are being used to monitor SIS performance and risk

Managers need to understand the ramifications of cost-cutting, especially when it comes to process safety and/or mechanical integrity

Managers need to be trained in understanding what Process and Functional Safety is all about – ignorance is no excuse

# Functional Safety Management Objectives

Leverage quality programs already in place.

Specify management and technical activities during the Safety Lifecycle to achieve and maintain Functional Safety

Specify responsibilities of people, departments and organizations

How?

- Appoint one or more people to lead FS activity
- Extend an existing monitored quality system
- Develop FS-related procedures
- Plan, execute, audit and improve (conduct Functional Safety Audits)

# How To Deal With Legacy Systems?

# Legacy Systems

Making sure Corporate Risk Guidelines exist

Need to start by reconsidering PHA and LOPA; PHAs have to be revisited every 5 years under OSHA

PHA needs to consider all hazards (especially if there have been incidents and/or near misses during the 5 year period)

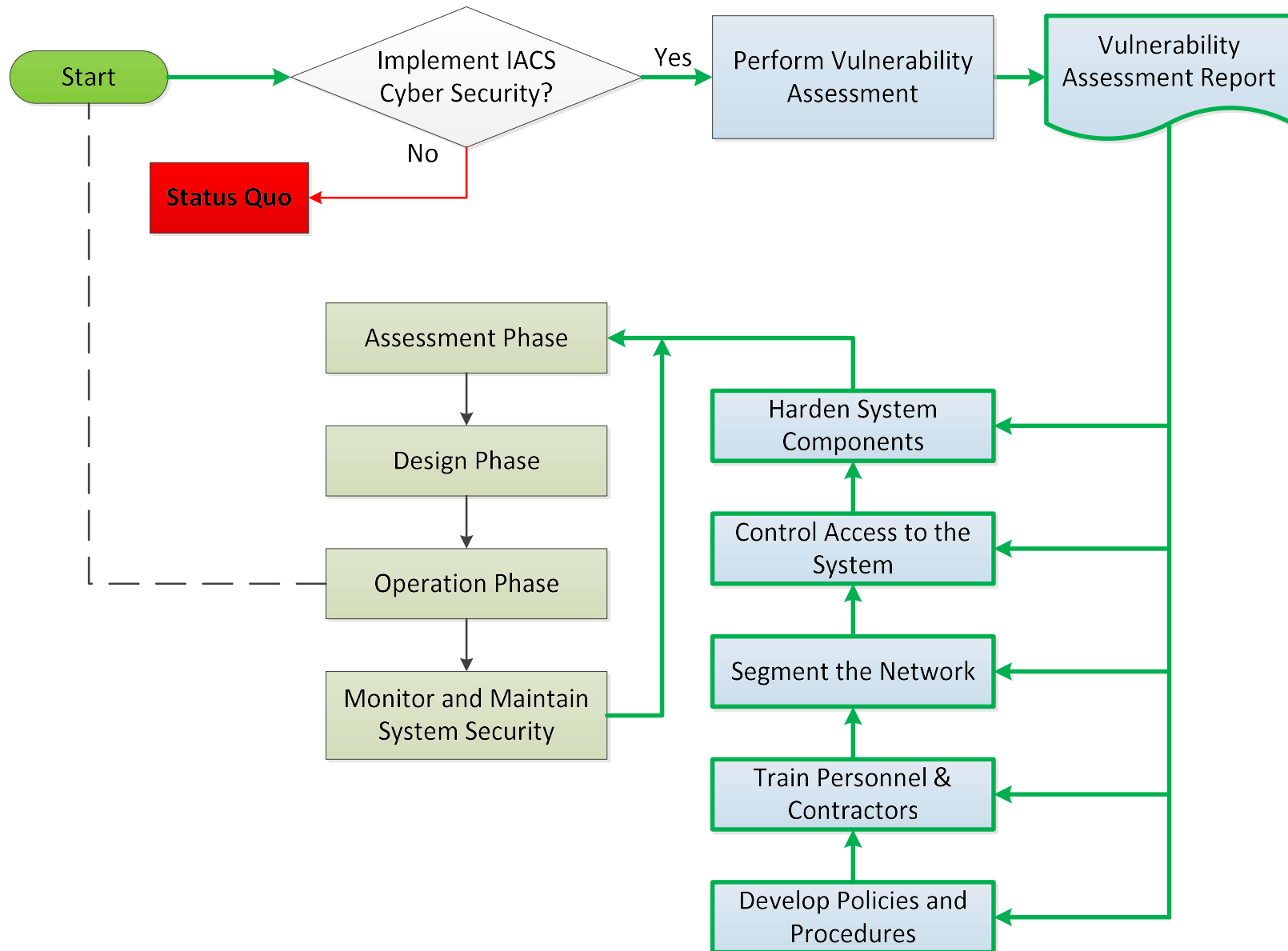
LOPA needs to consider highest consequence hazards and existing IPLS to assess further risk reduction

Legacy systems can be made to be compliant by replacing non-certified with certified devices at end of useful life

Mechanical integrity program needs to consider useful life, beyond which replacement/refurbishment is required

Reverse engineering legacy systems to create an SRS is possible, if good documentation and test/maintenance records exist; if not then time consuming and costly

# Entering Lifecycle as Brownfield Site



# Summary

IEC61511 defines that a Functional Safety Management System be put in place to manage the Safety Lifecycle activities

Having the right Safety Culture is imperative; management has to understand and support FSM or it won't work

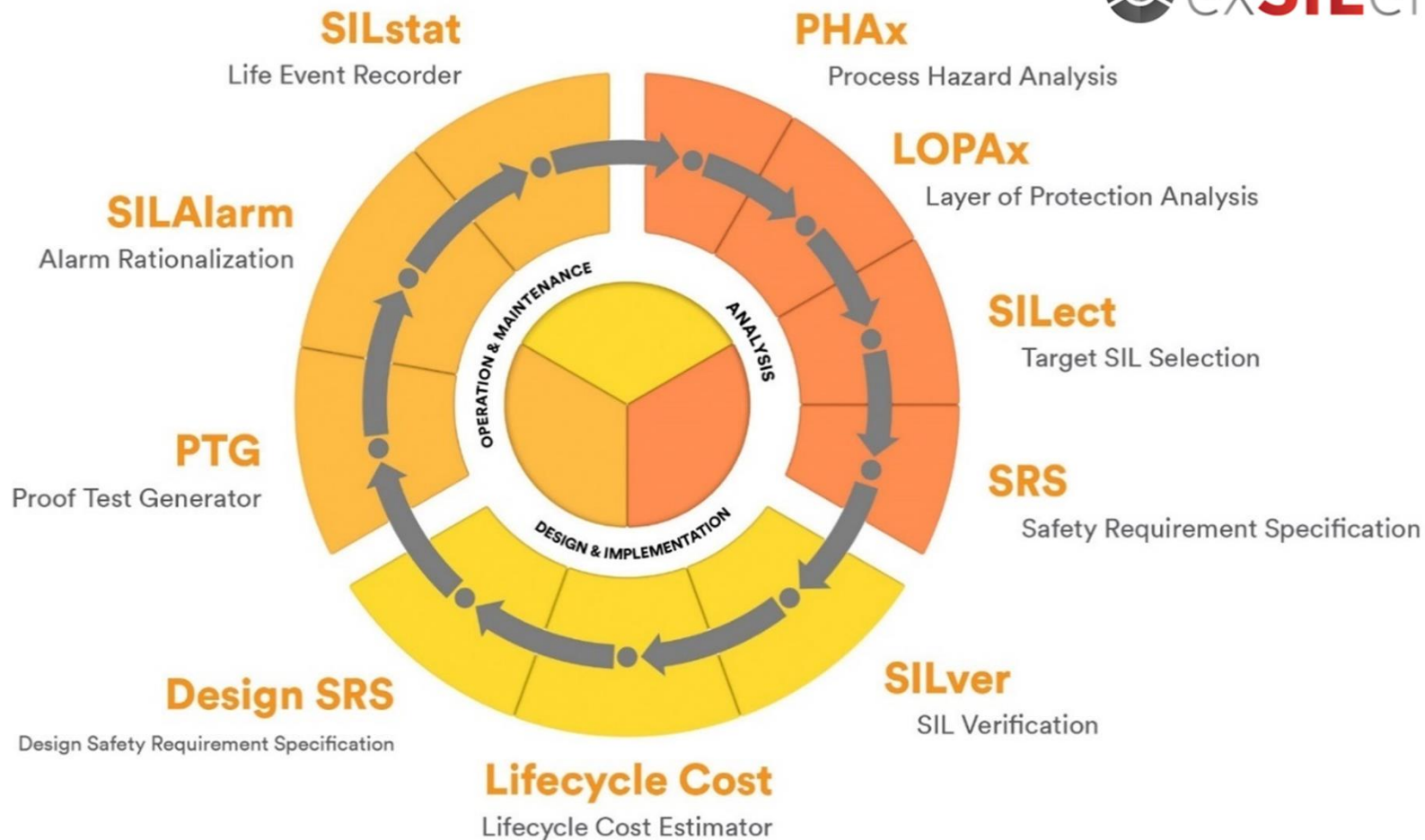
People, Procedures and Processes must be covered by any FSM system to ensure protection against systematic errors

Functional Safety Assessments and Functional Safety Audits are required to ensure that procedures and processes are being followed correctly to help safeguard against systematic errors

Competency is a key part and maintaining a matrix is a good approach to plan training



# Intelligent Lifecycle Integration



# If You Think Safety's Expensive

## Then Try an Accident!



# Questions?

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