Abstract

Many companies are in the process of validating or updating their asset integrity management program for safety instrumented systems with the intent of achieving the performance standards in ISA 84.00.01, *Functional Safety: Safety Instrumented Systems for the Process Industry*. It is a challenge to determine the best organizational structure, the relevant roles and responsibilities, and the training or skills of individuals in key positions to execute the Safety Lifecycle workflow.

Some companies are setting up groups within their engineering organizations; others are expanding their reliability or maintenance departments. Still others are assigning the leadership roles in the process safety departments. In truth, execution of the Safety Lifecycle, as with the Process Safety Standard 29 CFR 1910.119, requires an integrated workflow across multiple disciplines and areas of practice.

The author will outline the organizational characteristics of a strong Functional Safety Program and the roles to be filled to predictably execute the full Safety Lifecycle and achieve the related risk management objectives. These roles will be outlined in terms of responsibilities, technical and business acumen and training, and interpersonal skills relevant to success.

Introduction

Corporations globally are striving to comply with the Functional Safety Lifecycle requirements of IEC61511/61508 and ANSI/ISA 84.00.01 to achieve the overall objective of managing the integrity of their safety instrumented systems. This emphasis comes on the heels of downsizing central engineering organizations and the midst of a highly competitive market for experienced instrumentation and control (I&C) and process safety engineers. Integrated execution of the Safety Lifecycle to achieve the intended objectives and maximize the business value requires a cross-functional organization working together with a common vision.
This paper summarizes the requirements of the Functional Safety Lifecycle with emphasis on the competencies of the team of administrative, engineering, operations, and maintenance professionals necessary to develop and implement a sound management system.

**Summary of the Functional Safety Lifecycle**

The functional safety lifecycle is illustrated in Figure 1 below.

![Figure 1 Functional Safety Instrumented System Lifecycle Work Flow](image)

There are 19 clauses in the ANSI/ISA 84.00.01 standard which can be generally categorized into three phases; Risk Analysis, Realization, and Operation.

- **Risk Analysis** – Includes the identification and understanding of the hazards present, the challenge to apply inherent safety, and the definition/optimization of independent engineered and administrative safeguards to meet an organization’s tolerable risk criteria.

- **Realization** – Includes safeguard validation, detailed engineering, procurement, automation, installation and commissioning, pre-startup safety review, and functional safety assessments. This phase also includes integration of critical IPLs into operating procedures, training, maintenance programs, and process safety information.
• Operation – Includes operation, maintenance, bypass management, and management of change of safety instrumented functions (SIFs) and non-SIF IPLs. It also includes the collection of reliability data, auditing, reporting on performance metrics, and active risk management.

Organizations subject to US Occupational, Safety and Health Association’s (OSHA’s) process safety standard, 29 CFR 1910.119, US Environmental Protection Agency’s (EPA’s) risk management standard, 40 CFR 68, or other global process safety standard, implemented hazard analysis and risk assessment programs in the mid 1990’s. What has taken place in the last 10 years is an emphasis on risk-based process safety management as a means of prioritizing investments with limited resources and capital. This has driven companies to establish clear risk tolerance criteria as the bases for making sound, consistent, defensible business decisions. The risk tolerance criterion is typically in the form of a risk matrix with severity and frequency scales.

Clause 8 of ANSI/ISA 84.00.01 links the design basis of safety instrumented systems to an organization’s risk tolerance criteria. The design basis of a safety instrumented function is quantified as a probability of failure on demand and achieves a reduction of the frequency or likelihood that an initiating event will propagate forward to a loss of containment or consequence of concern. PHA methodology is used to identify the hazards present for a process, the initiating events considering failure of administrative and engineered systems, the potential consequences without safeguards, and a qualitative assessment of the mitigated event likelihood or frequency with safeguards. Organizations are then using the semi-quantitative layer of protection analysis (LOPA) methodology, or more rigorous forms of numerical analysis, to quantify the risk reduction credit of non-SIS independent protection layers (IPL). The mitigated event likelihood is compared to the tolerable mitigated event likelihood, with the difference documented as the basis for design of the related safety instrumented function, or SIS IPL.

Clause 9 defines the calculation methods, architectural constraints, and hardware fault tolerance that are to be taken into account when defining the SIF. This front end loading (FEL) engineering work requires competencies in mathematical methods, dynamic process control, instrumentation and control architecture, and control processors (logic solvers or programmable logic controllers) and communication highways. The SIS FEL phase of engineering also requires input from a strong process engineer capable of defining the process safety time of an event from cause to consequence and working with the SIS engineer to optimize the SIF with an understanding of the process dynamics and response to a trip.

Clause 10 requires the functional safety requirements to be documented in the form of a specification as the basis for detailed design and engineering.

Clause 11, 12, 13, 14, and 15 identify the requirements for the detailed engineering, factory acceptance testing, installation, commissioning and validation of an SIS system before turnover to operations.

Clause 16, 17 and 18 identify the requirements for the continued operations and maintenance of a SIS System. These requirements include management of change, procedure development, operator and maintenance training, as well as the testing, demand tracking, and auditing of each safety instrumented function.
Clause 19 identifies the document control measures intended to be in place relevant to executing the lifecycle activities.

**Organizations**

**Requirements**

Per Section 5.2.2.2 of ANSI/ISA 84.00.01, “Persons, departments or organizations involved in safety life-cycle activities shall be competent to carry out the activities for which they are accountable.

NOTE: As a minimum, the following items should be addressed when considering the competence of persons, departments, organizations or other units involved in safety life-cycle activities:

a) engineering knowledge, training and experience appropriate to the process application;
b) engineering knowledge, training and experience appropriate to the applicable technology used (for example, electrical, electronic or programmable electronic);
c) engineering knowledge, training and experience appropriate to the sensors and final elements;
d) safety engineering knowledge (for example, process safety analysis);
e) knowledge of the legal and safety regulatory requirements;
f) adequate management and leadership skills appropriate to their role in safety life-cycle activities;
g) understanding of the potential consequence of an event;
h) the safety integrity level of the safety instrumented functions;
i) the novelty and complexity of the application and the technology.”

The analysis phase of the Safety Lifecycle includes the more traditional risk analysis studies (e.g. PHA and LOPA), identification of SIS and non-SIS IPLs, as well as the front end loading (FEL) of the SIS system. Risk Analysis requires a lead facilitator with strong hazard analysis and risk assessment skills, as well as knowledge of administrative and engineered safeguards typically in place at operating facilities. These are usually found in individuals in either a process safety department or process engineering department.

SIS FEL includes SIF definition and logic narratives, SIL calculations and cause and effects. The engineer involved in SIF design requires a strong understanding of the criteria for independence, specificity, integrity, and auditability required to substantiate risk reduction credit. Complex SIFs actually require an understanding of fault tree analysis and quantification of common failure mode issues. Optimal SIF design also requires the engineer to be a strong communicator and collaborative leader who can work with the process safety professional that led the risk analysis, as well as the unit process engineer, controls engineer, operations representative, and mechanical engineer.

Realization activities follow a more traditional work flow for engineered capital projects involving instrumentation and controls from the design basis established in the FEL to detailed design, procurement, automation, factory acceptance testing, installation, commissioning, pre-startup safety review and turnover. The Risk Analysis phase is often expensed, while the Realization phase is
capitalized. These tasks may be addressed by capital project managers and control project engineers who have experience in the design and installation of process control systems in concert with process engineers and operations representatives who understand the process dynamics.

The Operations and Maintenance phase requires the focus of personnel who have competing priorities on critical safety functions. It can be used to prioritize limited financial and administrative resources toward those layers of protection which control an organization’s societal and financial risk.

**Functional Organizations**

Organizations subject to process safety standards typically have individuals with core competencies in the following areas:

- Process Safety
- Process Engineering
- Mechanical Engineering
- Process Instrumentation and Controls
- Maintenance and Reliability
- Project Engineering
- Operations

These companies have written management systems and functional organization for addressing the following process safety prevention program elements related to the Functional SIS Safety Lifecycle:

- Process Hazard Analysis
- Process Safety Information
- Mechanical Integrity
- Management of Change
- Operating Procedures
- Training

The challenge is to integrate the execution of the Functional SIS Safety Lifecycle with these personnel, or a minimal number of additional staff additions. Figure 2 presents the functional relationship of organizational groups that participate in the implementation of the Safety Lifecycle as a function of responsibility, accountability, consulted and informed, or RACI. Corporate groups set the risk criteria and minimum expectations. Plant Management owns the compliance with these requirements and the applicable standards. The Plant Manager generally delegates the responsibilities for specific activities down to representatives from the functional groups identified.

Table 1 further outlines the personnel called on from each group, their safety lifecycle related work products, and the suggested experience and skills necessary to competently perform in these roles. After assessing the overlap of the competencies of the existing personnel with those identified in Table
Plant Managers may elect to delegate the responsibility for execution of the complete lifecycle to either the Process Safety Department Manager or the Engineering Department Manager. Either can be successful, but only to the degree that they can integrate the energy and resources from the other department, operations and maintenance. As with any cross-functional program, this requires knowledgeable and mindful leadership from the highest levels of management to the frontline supervisors.

Figure 3 illustrates a typical functional organization structure for executing the Safety Lifecycle.
<table>
<thead>
<tr>
<th>Functional Group</th>
<th>Management</th>
<th>Risk Analysis</th>
<th>Realization</th>
<th>Operations and Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>A – Accountable/Approver – Has overall accountability to establish and implement management systems to meet the company risk management strategy and approval authority.</td>
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<td>R – Responsible – Has responsibility to execute the work and see that the minimum requirements are met and scope completed. May perform the work or just coordinate it.</td>
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<td>C – Consulted – May perform a portion of the work or provide input necessary to complete it. Participates as a member of the team as directed by the “Responsible” lead or manager.</td>
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<td>I – Informed – Receives output of others necessary to perform their job function or to maintain a state of awareness and feedback.</td>
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<td>'-' – No involvement</td>
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</table>

### ISA-84.01-2004-1 Clause

**Clause 5 – Identify the management activities that are necessary to ensure the functional safety objectives are met.**

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<tr>
<td>A R C C C C C I I C C C</td>
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</table>

**Clause 6 – Define safety lifecycle phases incorporating standard requirements including technical activity inputs, outputs, and verification steps required to meet the safety requirements.**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 8 – Hazard and risk assessment (Layers of Protection Analysis, Layered Risk Analysis, etc.) and Clause 9 – Allocation of safety functions to protection layers.**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 10 – SIS safety requirement specification (SRS).**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 11 – SIS design and engineering.**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 12 – Requirements for application software, including selection criteria for utility software.**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 13 – Factory acceptance test (FAT) informative not normative.**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 14 – SIS installation and commissioning.**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 15 – SIS safety validation (SAT).**

| ISA R C C C C I I I C C C | | | | | | | | | | | | |

**Clause 16 – SIS operation and Maintenance (Procedures, Training, Testing, Demand Tracking, Auditing).**

| ISA R C C C C I | | | | | | | | | | | | |

**Clause 17 – SIS modification.**

| ISA R C C C C I | | | | | | | | | | | | |

**Clause 18 – SIS decommissioning.**

| ISA R C C C C I | | | | | | | | | | | | |

**Clause 19 – Information and documentation requirements.**

| ISA R C C C C I | | | | | | | | | | | | |

Note 1: Capital Project Manager/Engineer has the responsibility to deliver the project on scope, schedule, and budget (Clause 11 – 15). The SIS Engineer is “Responsible” for validating the SIS installation during commissioning and prior to startup, i.e. completing the Stage 3 FSA. Many organizations are assigning Capital Project Controls Engineers with background in instrumentation and control system installation and commissioning.

**Figure 2: RACI Diagram for SIS Safety Lifecycle Implementation**
<table>
<thead>
<tr>
<th>Functional Group</th>
<th>Positions/Roles Involved</th>
<th>Safety Lifecycle Work Products</th>
<th>Experience or Skills</th>
<th>Training and Development Opportunities</th>
</tr>
</thead>
</table>
| **Corporate Process Safety Governance** | EHS & Manager, PS Director/Manager, SIS Technical Authority Corporate Consultant | • Tolerable Risk Criteria  
• Compliance Strategy  
• Tier 1 and Tier 2 Management Systems  
• Functional Safety Plan | • Process Safety Implementation  
• Knowledgeable in Risk Analysis and PHA/LOPA Methodology  
• Experience in specific process hazards related to business areas  
• ANSI/ISA 84.00.01 or IEC 61511/61508 Awareness  
• PS/Lifecycle Performance Metrics | • Process Safety Awareness Training  
• ANSI/ISA 84.00.01 SIS Lifecycle Awareness Training  
• PHA/LOPA Facilitator Courses or Meeting Participation  
• Incident Investigation Training and Participation  
• PS Auditing or ISA/IEC Gap Assessment Training and Participation |
| **Plant Management** | Plant Manager, Process Unit Operations Manager | • Approved Functional Safety Organization Chart  
• Job Descriptions with PS/SIS Roles and Responsibilities  
• PS/SIS Metrics and Goals  
• Approved Tier 3 Safety Lifecycle Management Procedures  
• PHA/LOPA Recommendation Mgmt.  
• Project Review/Approval | • Process Safety Principles  
• Inheren Safety Principles  
• Knowledgeable in Risk Analysis and PHA/LOPA Methodology  
• Experience in specific process hazards related to business areas  
• Understanding of corporate Functional Safety Plan  
• PS/Lifecycle Performance Metrics  
• Capital Project Management  
• Operational Excellence  
• Asset Reliability Management | • Primarily an accumulation of experiences  
• Process Safety Awareness Training  
• ANSI/ISA 84.00.01 SIS Lifecycle Awareness Training  
• Incident Investigation Training  
• Maintenance/Reliability Management Awareness Training |
| **Process Safety (PHA/LOPA/PSM)*** (Risk Analysis) | PSM Manager, PHA/LOPA Facilitator, PHA/LOPA Coordinator, MOC Coordinator | • PHA/LOPA Facilitation and Report  
• SIS Design Basis  
• IPL Inventory  
• Critical Equipment and Procedure List  
• PS/SIS Performance Tracking and Reporting  
• MOC Management  
• PS Recommendation Tracking and Reporting | • Process Safety Implementation  
• Risk Analysis and PHA/LOPA Methodology  
• Consequence Assessment  
• Knowledgeable in common mode/cause failures  
• ANSI/ISA 84.00.01 or IEC 61511/61508 Awareness  
• PS/Lifecycle Performance Metrics  
• MOC  
• IPL Identification and Management  
• Maintenance and Reliability Management  
• Operating Procedures and Operator Training | • Process Safety Awareness Training  
• ANSI/ISA 84.00.01 SIS Lifecycle Awareness Training  
• PHA/LOPA Facilitator Courses or Meeting Participation  
• ANSI/ISA 84.00.01 Awareness Training  
• Consequence Assessment Training  
• Quantitative Risk Assessment Methods |
| **SIS Engineering (Realization)** | SIS Team Leader, SIS Group Leader, SIS I&E Engineer | • SIF Architecture  
• SIL Calculations  
• Cause and Effects  
• Logic Narratives  
• Safety Requirements Specification  
• Capital Request Scope and Cost Estimate  
• Oversight of SIS System Integrators and Contractors  
• Instrument Specifications  
• Installation Specifications  
• Factory Acceptance Test Plan  
• Functional Safety Assessments  
• Proof Test Plans  
• Demand Tracking | • Instrumentation and Controls Engineering  
• Project Engineering/CAE Project Experience  
• Instrument Maintenance/Reliability Experience  
• Process Safety Principles  
• Applicable Risk Criteria  
• Inherent Safety Principles  
• Knowledgeable in Risk Analysis and PHA/LOPA Methodology  
• SIS/Life Safety and SIL Gap Assignment  
• ANSI/ISA 84.00.01 or IEC 61511/61508 formal training on SIF Design and Maintenance  
• Knowledgeable in device common mode/common cause failures  
• MOC  
• Data Management Techniques | • Project Management Training  
• Process Safety Awareness Training  
• ANSI/ISA 84.00.01 SIS Lifecycle Awareness Training  
• ANSI/ISA 84.00.01 Certification Training Courses (e.g. ISA, CFSE, TÜV)  
• Reliability Data Management Course  
• PHA/LOPA Team Participation  
• ISA 18.2 Alarm Management Awareness Training |
### Table 1 (Cont.): Functional Group Positions, Work Products, Skills and Training Requirements to Implement the SIS Safety Lifecycle

<table>
<thead>
<tr>
<th>Functional Group</th>
<th>Positions/Roles Involved</th>
<th>Safety Lifecycle Work Products</th>
<th>Experience or Skills</th>
<th>Training and Development Opportunities</th>
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</thead>
<tbody>
<tr>
<td>Training Specialists</td>
<td>• Process Safety Times</td>
<td>• Process Design Parameters</td>
<td>• Operator Training on Procedure and Alarm Response</td>
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<tr>
<td></td>
<td>• Operator Response Times</td>
<td>• Knowledgeable in Risk Analysis and PHA/LOPA Methodology and SIL Gap Assignment</td>
<td>• SIS System Interface Training</td>
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<td></td>
<td>• Approval of Cause and Effects and Logic Narratives</td>
<td>• ANSI/ISA 84.00.01 or IEC 61511/61508 Awareness</td>
<td>• Integrity/Reliability Data Awareness Training</td>
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<td></td>
<td>• Capital Project Review Approval</td>
<td>• Operating Procedures and Response to Diagnostic and Critical Alarms</td>
<td>• Safety Function Bypass Management Training</td>
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<td></td>
<td>• Alarm and Operating Procedure IPL Validation and Maintenance</td>
<td>• Operator Training</td>
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<td></td>
<td>• Operator Training on IPLs</td>
<td>• Cause and Effects</td>
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<td></td>
<td>• Demand Record Keeping</td>
<td>• Logic Narratives</td>
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<td></td>
<td>• Initiating Cause Record Keeping</td>
<td>• Understanding of Integrity/Reliability Data</td>
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<td>• Bypass Management</td>
<td>• MOC</td>
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<td>• Work Order Request</td>
<td>• Bypass Management</td>
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<td>• MOC</td>
<td>• Incident Investigation (on demand)</td>
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<td></td>
<td>• Input on Mechanical Installation</td>
<td>• PS/SIS Lifecycle Performance Metrics</td>
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<td>• Critical Equipment and Procedure Maintenance</td>
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| Maintenance and Reliability (Operations and Maintenance) | I&C Reliability Specialist | PHA/LOPA Team Member | • Process Safety Awareness Training |
| | Fixed and Rotating Equipment Reliability Specialist | • Provide Failure Modes and Effects of Equipment | • ANSI/ISA 84.00.01 SIS Lifecycle Awareness Training |
| | Instrument Technician | • Provide Historical Reliability Data | • SIF Proof Test Planning, Execution and Record Keeping |
| | Maintenance Coordinator | • Perform Proof Test Plans | • Integrity/Reliability Data Awareness Training |
| | | • Record Keeping of Test Results and Maintenance Activities | • Safety Function Bypass Management Training |
| | | • Initiate Near Miss Reporting if Loop is found in a Failed State | • Mechanical Integrity Quality Management Training |
| | | • Repair within 72 Hours |  |
| | | • Spare Parts Management | |

**Acronyms:** Process Safety (PS), Process Safety Management (PSM), Process Hazard Analysis (PHA), Layer of Protection Analysis (LOPA), Safety Instrumented System (SIS), Instrument Society of America (ISA), International Electrotechnical Commission (IEC), Independent Protection Layer (IPL), Management of Change (MOC), Certified Functional Safety Expert (CFSE), Factory Acceptance Test (FAT) Plan, Functional Safety Assessment (FSA), Safety Instrumented Function (SIF)
Figure 3 Functional Safety Instrumented System Lifecycle Organizational Work Flow
**Training and Development**

There are many overlapping requirements between the SIS Lifecycle standards and the process safety standards in the US and abroad. To meet the objectives intended by the standards and achieve the valued outcome, individuals that are assigned safety life-cycle activities require various forms of training and experience.

Suggested training and development requirements for personnel involved in safety lifecycle activities are presented in the final column of Table 1. All require the pre-requisite professional education and experience relevant to their positions. Several have very specific training program recommendations such as PHA/LOPA Facilitator Training for process safety professionals responsible for the Risk Analysis requirements.

There is a common need for the following courses for all involved so that they might better understand their individual roles and responsibilities:

- Process Safety Awareness Training
- ANSI/ISA 84.00.01 SIS Lifecycle Awareness Training.

There are commercial classes available for both of these. As organizations develop Tier 1 and Tier 2 Management Systems at a corporate level these courses are most effective if they are customized to consistently reinforce the performance based expectations to all involved.

The two skill sets unique to implementing the SIS Safety Lifecycle are:

- SIS Engineering - ANSI/ISA 84.00.01 Certification Training Courses
- SIS Reliability and Maintenance - Safety Instrumented Function Proof Test Planning, Execution and Record Keeping.

Facilities can and do outsource contractors that have certifications and competency in these areas to handle capital projects and peak loads, augment staff, or support and mentor internal staff development. However, with the number of interface points in the organization to fully execute the lifecycle and optimize the work flow, as well as the financial investments that are being made in safety instrumented systems, it is strategic to build a degree of in-house capacity in SIS Engineering, Reliability and Maintenance. There are training programs available through universities, consultant organizations, and ISA. There are also the following certification programs that have tiered levels of recognized competency:

- ISA 84 Safety Instrumented System (SIS) Expert - ISA
- Certified Functional Safety Expert (CFSE) – exida
- Functional Safety Expert (FSExp) – TUV Rheinland
Summary and Conclusions

In summary, the skills and competencies of individuals currently in roles associated with achieving an organization’s process safety goals and objectives are well aligned with those necessary to achieve compliance with the SIS Safety Lifecycle requirements of IEC61511/61508 and ANSI/ISA 84.00.01. In addition to their core competencies, it is important that all personnel assigned a responsibility for safety lifecycle activities have awareness level training so they understand their role and contributions. This training should clearly present the corporation’s risk criteria and programmatic plan for executing the SIS Safety Lifecycle.

There are two distinctly new competencies necessary to achieve and sustain compliance; 1) is SIS Engineering with prescriptive calculation methods and deliverables, and 2) SIS Reliability and Maintenance with component testing, record keeping, and compilation of a historical reliability database. These are competencies that are closely aligned with those of existing instrumentation and control engineers and reliability specialists that have been actively involved in capital projects for units subject to the process safety standards. However, individuals’ assigned responsibilities in these areas require external training to perform or direct the work of others. They also require strong interpersonal skills to leverage that experience to others involved in executing lifecycle tasks.

Companies may elect to divide and delegate the responsibilities for executing the Safety Lifecycle to group managers in their existing process safety, engineering and maintenance organizations. However, the complexity of executing the full lifecycle requires a programmatic focus and vision of how it overlays with an organization’s process safety management program. For that reason, effectively executing the SIS Safety Lifecycle from Risk Analysis thru Realization and Operations and Maintenance requires an internal champion. Companies that are making strides in accomplishing the objectives of the SIS Safety Lifecycle are identifying that champion, and either making them a Group Manager, assigning them a dedicated team of personnel from the other groups, or establishing partnerships with knowledgeable contractors to execute the Safety Lifecycle across the high hazard process units.