Delivering a Periodic Functional Safety Assessment in the Industrial Process Operational Phase

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Abstract -
Historically, the way in which safety instrumented systems have been operated and maintained can vary significantly. Essentially whatever methodologies are deployed within the operation, the use of a proper lifecycle management approach will be required to maintain the necessary levels of risk reduction.

When modifications are applied to the SIS over time, the requirements for change management, impact assessment and functional safety assessment will need to be implemented. The basis of safety will need to be re-evaluated and the safety requirements updated along with the current 'As Built' documentation.

IEC 61511 recognises that 'periodic functional safety assessment' within the SIS O&M lifecycle phase is mandatory to support the successful functional safety management and delivery of the necessary risk reduction. This paper will identify what is reasonable and practicable to include and assess while operating, maintaining, modifying and testing this important layer of protection.

Index Terms – Functional Safety Management, Functional Safety Assessment, Periodic, Safety Lifecycle, IEC 61508, IEC 61511, Safety Instrumented System.

I. Introduction

Today many process industry company standards ask for specific requirements to be met in order to manage the maintenance, testing, inspection, and performance analysis of the operating facilities. basis of functional safety.

As part of 'overall safety' for the operating facility, effective safety related systems operation, maintenance, inspection and associated proof testing should confirm the correct operation of the devices deployed and in doing so, detect dangerous hidden faults in such protective barriers.

Ultimately, the Asset Owner will need to know if they can 'demonstrate' the operation and maintenance of SIS is in compliance to recognised industry good practice standards such as those for safety instrumented systems i.e. IEC 61508, IEC 61511 or ISA84 and the associated requirements to meet any regulatory / business insurer expectations.

This important 'protection layer' clearly needs to be managed and delivered against current process industry challenges such as e.g.:

- Compliance to industry code or practice
- Changing market conditions
- Ever increasing production norms
- Lean operational resources
- Increasing regulatory and business insurer expectations on what is good safety
- Sustaining the basis of safety over time and change management
- Cost reduction mandates
- Maintaining focus on process safety leadership and culture

As a means to ensure the operating basis of safety is being maintained, the IEC 61511 safety lifecycle identifies the need for the duty holder to undertake a periodic review of the management process and the technical verification of current site safety requirements being implemented to meet operational risk reduction needs.

For the operation and maintenance (O&M) phase of the safety lifecycle, part of this assurance process will be afforded by the need to undertake a '*Stage 4 Functional Safety Assessment'* for the specific Asset.

There is also the relationship to the broader process safety picture where SIS form part of 'overall safety' regarding the operating facility complete risk reduction measures e.g. operating in conjunction with other technology systems such as machinery & power drives, mechanical relief and blowdown systems, containment systems, etc.

Typically, a review of the basis of safety for the operating facility will be undertaken on a periodic frequency of between 3-5 years, and therefore it would be appropriate that the requirements of Stage 4 FSA for SIS would practically be a sub-set of the more comprehensive process safety review.

It could also be observed that the topics required for SIS Stage 4 FSA could be extended to facilitate the auditability requirements for any protection layer (either instrumented / non-instrumented or control / prevention functions) of overall safety dependent on the composition and technical coverage / depth of the assessment team undertaking the more holistic review. This would be appropriate as Stage 4 FSA will require the same site-based input and responses from EHS, Process, Engineering, Operation & Maintenance and Management teams that are available at site.

II. Significance of stage 4 FSA

Within manufacturing facilities today, there are known to be a wide range of techniques and methods adopted

by the end-user community in their approach to safety system operation, maintenance, inspection, proof testing and modification.

There is too, the previously mentioned desire to comply with industry good practice standards particularly for safety instrumented systems (SIS) such as IEC 61508 and IEC 61511. Here, broadly speaking, it is now accepted good practice to follow the requirements of these standards to show that the necessary protective systems are being operated, maintained and tested in accordance with details as identified within the original safety requirements specification (SRS), and its subsequent change management revision over time.

Experience also suggests, that during planned site visits regarding compliance auditing and assessments to relevant good practices, both internal company and external stakeholders are increasingly showing an interest in the duty holders' operation, maintenance, proof testing and change management regimes. In particular, for documented evidence of the organisation having undertaken an IEC 61511 stage 4 FSA.

The basis of safety delivered by SIS will need to be re-evaluated against the SRS along with the current 'As Built' documentation. Any supporting preventative and corrective maintenance measures will need to be scheduled and executed in accordance with device safety manuals.

When modifications are applied to installed protective systems, the requirements for change management, impact assessment and functional safety assessment will need to be implemented.

Such processes will need to consider as a minimum:

- Proper operation and maintenance planning for such safety related systems
- Procedures and instructions for O&M of the SIS
- Demonstration of compliance to the relevant functional safety standards
- Functional Safety management compliance demonstration including the key structural requirements for:
    - Management Process (Policies, Procedures & Records)
    - Competency Assurance
    - Audit and Assessment

III. Requirements for Functional Safety Assessment

IEC 61511 specifically requires: at clause 5.2.6.1.4 that "*the stages in the SIS safety life-cycle at which the FSA activities are to be carried out shall be identified during the safety planning*, and in particular for Stage 4 FSA, *after gaining experience in operating and maintenance".*

Further, clause 5.2.6.1.10 identifies that an "*FSA shall also be carried out periodically during the operations and maintenance phase to ensure and operation are being carried out according to the assumptions made during design and that the requirements within IEC 61511 for safety management and verification are being met".*

Figure 1 below provides an overview of the IEC 61511 lifecycle and the identified 'stages' for functional safety assessment to be carried out and the focus for this paper regarding Stage 4 FSA.

Here we also need to recognise the difference between an 'Audit and an 'Assessment' in the context of the standard. We identify that an Audit is the determination as to whether the company operational procedures and practices are being followed consistently and whether the overall management program is working effectively, whereas, an Assessment is different in as much its emphasis is to undertake a detailed technical and management focused investigation to judge the functional safety achieved by the relevant protection layers under review.

So, given the role and importance of this specific activity, how are you meeting the requirements of periodic Stage 4 FSA in your organisation?

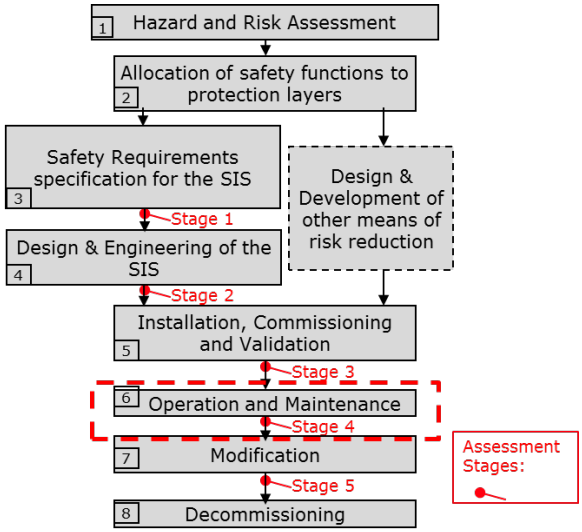

Figure 1 – IEC 61511 Safety Lifecycle and FSA Stages

IV. Management Process and FSAs

As the IEC 61511 standard focuses predominantly on SIS, it identifies that *a '"functional safety management system shall be in place so as to ensure that where safety instrumented systems are used, they have the ability to place and/or maintain the process in a 'safe state"* and by association this means that '*there shall be in place systems & procedures that cover the requirements for proper operations & maintenance to ensure:*

- *The designed SIS functionality is maintained*
- *The required SIL of each SIF is maintained during operation and maintenance"*

Further, many years of experience in the development and assessment of operational management procedures across a range of operating sectors within the process industries, identifies that in several cases, robust management processes can be found to be lacking or contain significant gaps in good practice expectations.

Observations regarding process and underpinning senior management commitment to achieve functional safety excellence in this area concludes that:

- Many QMS as per ISO 9001 lack sufficient depth and rigour even for baseline management requirements (greater reliance on individual competencies rather than any codification of requirements)
- Many management systems are disconnected between various departments that can cause issues on process delivery and effective communication requirements
- Some management systems cannot be shown to comply with expected industry good practice standards/guidance
- Many process industry statistics show that errors, omissions and incidents are directly attributable to a lack of robust management system/process and internal commitments to sustain them
- Many management processes are implemented and then receive little attention once in place
- Stakeholders expect robust management processes to be in place and will require the duty holder to demonstrate that this is the case
- There is some evidence that it is common practice for companies to ignore the requirements for undertaking Stage 3 FSA

It therefore follows that the IEC 61511 standard requires for periodic assessments to be conducted to address the issues identified above to ensure safety integrity and security measures are as implemented and that they continue to provide the necessary risk reduction for the operational facility.

V. WHAT SHOULD BE INCLUDED IN YOU PERIODIC FSA?

A Functional Safety Assessment (including the management process requirements of system auditing) is identified as a systematic and independent examination of the particular SIS safety lifecycle phases activities under review and as in this case the operation and maintenance lifecycle phases of the safety lifecycle.

In accordance with IEC 61511 requirements, this periodic FSA approach will determine whether the management process and technical activities comply with the planned arrangements, are implemented effectively, and are suitable to achieve the specified objectives.

Performing FSAs requires personnel with a high level of competency and is more often than not based on subjectivity, particularly when applied to the earlier phases of the safety lifecycle. A further key consideration is the level of independence of the team performing the FSA and by implication, their assessors. The necessary level of independence shall comply with IEC 61508, Part 1, clauses 8.2.12 to 8.2.14 or IEC 61511 part 1, clause 5.2.6.1.2.

To set out to achieve this goal, those responsible for ensuring FSAs are conducted should establish and effectively manage the following key parameters:

- A Stage 1-3 / 4 FSA plan is developed and is being followed
- Competency and independence are addressed by those completing Periodic FSAs
- Requirements for developing a common approach to FSA topics requirements are met i.e. focus on what is most important.
- An approach is applied that is structured on compliance requirements to the basic safety standard IEC 61508-1, or the standard derived from IEC 61508 to which functional safety claims are made (e.g. IEC 61511)
- A methodology is agreed which would be useful to benchmark assessment findings in a speedy manner and provide a means for comparison between different process units/assets for company KPI's
- A repeatable process is utilised so that it can be used to track and monitor improvements and provide the necessary forwards/backwards traceability between differing assessments
- Harness the use of FSA support tools to quickly establish the process when undertaking assessments with busy operational resources and in a cost-effective manner

VI. ASSESSMENT METHODS FOR IMPROVING FUNCTIONAL SAFETY – REQUIREMENTS?

The methodology to be applied should identify a means to optimise the assessment process for the current performance status of the operational safety related systems. This means the use of a methodology that can be easily traced to industry good practice expectations whilst digitizing the operational status assessment process and findings for sustainable and traceable records.

Here, the Lead Assessor needs to ensure that the assessment process and subsequent results are readable, intuitive, and easily presented for understanding and adoption by all stakeholders. Nowadays, Lead Assessors can utilise specific database Tools for this purpose regarding the digitization of the FSA process.

The organisation that provides the Lead Assessor will need to deploy an assessment structure (procedures / instructions / process / tools) that is robust, repeatable and allows for the comparison and analysis of findings to support senior management focus and underpinning safety culture.

In doing so, this should provide a means to identify Key Performance Indicators (KPIs) for areas of non-compliance. Ultimately the Asset Owner needs to satisfy themselves that the FSA process / methodology to be applied essentially assesses if appropriate technical methods, techniques and measures, results and processes have been used to achieve the necessary functional safety.

From the author's experience, Stage 4 FSA methodology for SIS should consider the following 'Key Principles' topic areas:

- Functional Safety Management
- Competency Assurance
- Stage 1, 2 and 3 Assessments and Audits results and their implementations

- Management of Change
- Human Factors (systematic failures)
- SIS Cyber Security
- Pre-start-up / Ongoing Process Safety
- SIS Operation & Maintenance
- Planning / procedures to be applied on the system for detected faults
- SIS Inspections, maintenance & proof testing
- Operational performance and device mission time monitoring

So, what should be considered for assessment at the detail level under each Key Principle? As with this type of assessment, the Lead Assessor will open with a critical question and lead the assessment team down a structured narrative to explore the topic at the comprehensive level.

During the FSA team discussion, the assessment team will need to establish the associated 'sub-principle' criteria to be assessed and the findings recorded, compliance levels defined, and any recommendations made.

To fully describe and detail a complete FSA process would clearly be inappropriate for this paper. However, to further assist the reader in what may constitute a high-level overview of this recommended approach, the following section will provide a high-level introduction and a little more detail and thought processes to be applied for the Key Principles identified earlier.

This could be used as a means to demonstrate '*one example approach'* to achieve such a level of depth to be covered.

I) FUNCTIONAL SAFETY MANAGEMENT

Opening question:

Is the policy and strategy for achieving functional safety identified within the organisation?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Policy
- Roles and responsibilities
- Planning
- Procedures
- Competency
- Risk evaluation
- Verification
- Documentation

Here the assessor is seeking clarity on the management process and importantly management commitment to underpin its effectiveness.

A competency management system should be in place and there is a structure being used to periodically monitor and re-assess the performance of personnel in plant operations.

Risks associated with the operational hazards have been evaluated and documented.

II) COMPETENCY ASSURANCE

Opening question:

How does the site management team ensure that personnel have the correct level of knowledge, training and experience appropriate to their role, the plant process and technology deployed for the SIS?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Procedures
- Planning
- Understanding of Process and Technology
- SIS Functionality and Operation
- Operational Hazards
- SIS Devices Failure Modes
- SIS Bypassing

Here the assessor requires to know that competent persons are identified, assessed for their specific roles and responsibilities for safety related activities and that such competencies are recorded, reviewed and approved, including the need for any mentoring, training and supervision for the tasks assigned at the individual level.

III) AUDIT & ASSESSMENT

Opening question:

How are FS Audits and FS Assessments compliance requirements being met in the company?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Scope
- Procedures
- Planning
- Results and action tracking
- Assessors Competency & Independence

Here the assessor needs to establish that audits and assessments are planned, visible and communicated. It is important that competency and independence is established and that the results of such activities are actioned tracked with supporting management involvement to ensure their satisfactory conclusion.

IV) MANAGEMENT OF CHANGE

Opening question:

How are changes / modifications to any safety instrumented system planned, reviewed and approved?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Procedures
- Planning
- Impact assessment and analysis
- Competency of persons involved in modification
- Confirmation of effectiveness (reverification / revalidation and approval)

Here the assessor will be keen to establish that change management controls are robust and that impact assessments are being carried out for change approval by competent and independent approvers.

This will also include for version control and 'As Built' status updates across a range of documentation, technology, serialisation, etc. that are correct to reflect current operational status and that the basis of safety remains accurate and valid.

V) HUMAN FACTORS

Opening question:

How have the requirements for Human Performance and the impact of these requirements onto those persons responsible for operations and maintenance being implemented?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Policy
- Procedures
- Planning
- Safety critical tasks and risk assessment
- Task analysis and human reliability analysis
- Analysis reports on sub-task performance
- Requirements for highly managed alarms
- Control measures for human performance
- Investigation reporting

Here the assessor will be seeking to establish the requirements for the adoption of structured methodologies for undertaking human reliability analysis (HRA) on critical tasks for safety in line with relevant good practice and that the level of human involvement / interaction is understood with respect to the consequences of human failure.

VI) SIS CYBERSECURITY

Opening question:

How is the organisation's security policy defined, organized and executed?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Policy
- Risk Analysis
- Personnel security
- Physical security
- Network segmentation
- Account administration
- Authentication and authorization
- Information management
- Incident planning
- Monitoring and improvement

Here the assessor will identify the systems, processes and organisations involved in cyber security management (CSMS) for the SIS and confirm how the organisation understands the importance of security for its IT / OT operating environment.

A risk profile will have been established and applied across the technology in use which should have records and analysis of performance available. The organisation will also detail an incident response plan and that all employees have been trained to deal with cybersecurity breaches.

VII) PROCESS HAZARD AND RISK ANALYSIS

Opening question:

Is a comprehensive Hazard and Risk Analysis available for review, and if so, what does it contain?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Procedures
- Planning
- Safety function analysis / allocation
- Design assumptions
- Stage 3 FSA including implementation of findings
- Utilities
- Reliability assumptions
- Explosive atmospheres
- Control room suitability
- HMI

Here the assessor requires to establish that a description of each identified hazardous event exists and that the likelihood and consequences of each hazard is fully understood.

Where SIF protection layers exist, they are fit for purpose regarding the required risk reduction and that they are maintained and operated correctly (including supporting utilities) against safety requirements and design assumptions.

In addition, the threat of explosions and pressure bursts have been considered for control room operations and the HMI within this environment effectively informs the operating team of any deviations from normal safe operating levels.

VIII) OPERATION

Opening question:

How do the current operating procedures cover the comprehensive topics/key requirements for safe plant operation – what depth of operational detail/requirements do they cover?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Procedure range
- Procedure coverage
- How each plant mode of operation is addressed
- Procedure task analysis
- SIS Interface requirements
- SIF definitions
- Override management
- Behaviour on fault

Here the assessor will establish adequate consideration for the maintenance of the operating plant including such requirements during several modes of operation.

SIS operators have been effectively trained for such duties using approved method statement and routines. Root case analysis exists for failure consequences and demands on protective systems are recorded and analysed.

IX) MAINTENANCE

Opening question:

How are maintenance practices identified and managed for the operational facility?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Procedures
- Planning
- Practices
- Routine actions
- Repairs
- Sensors Calibration
- Records
- Spares
- Inspection

Here the assessor will establish the standard operating procedures and operating philosophy including the requirements for abnormal operating mode procedures.

The available operator information will need to provide the necessary status for effective protective barrier management and the basis of managing overrides and requirements for when faults occur.

X) PROOF TESTING

Opening question:

What constitutes a robust proof test procedure? Do they apply for every safety function across the facility?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Procedure
- Test coverage
- Test methods
- Failure modes to be addressed
- Diagnostics
- Security
- Records and analysis

Here the assessor will require to review that written proof test procedures are adequate for their intent and that the test coverage is commensurate to the safety functions available at site. Records need to exist for preventative and corrective maintenance including the requirements for management of change.

Testing is carried out against defined schedule and that any deferments are managed correctly. Failures and detected faults are recorded and analysed for improvement.

XI) OPERATIONAL PERFORMANCE AND DEVICE MISSION TIME MONITORING

Opening question:

How does the management team ensure that the performance of the safety critical assets is maintained and that they are fit for service at all times?

Sub-principle topics to be explored, evaluated and compliance levels agreed covering:

- Leadership
- Asset register
- Containment
- Critical equipment list
- Inspection and test
- monitoring of the demand rate on SIS
- monitoring of the rate of SIS failures
- the SIS spurious trip rate
- root cause analysis with subsequent changes to reduce systematic failures rates
- Obsolescence

Here the assessor will seek evidence of a comprehensive asset register which identifies safety critical equipment and that the register is current and up to date.

A mechanism should exist for identifying and highlighting equipment that due to operational factors may be subject to significant ageing. Such safety critical equipment needs to be monitored and managed effectively including relevant planning and resolution of system obsolescence.

XII) FSA REPORTING

Digitizing the results of the FSA process provides the opportunity to improve corporate memory and support information management needs. It also allows for the data to be displayed in various formats to suit several stakeholder requirements e.g. from high level summaries down to technical detailed reporting.

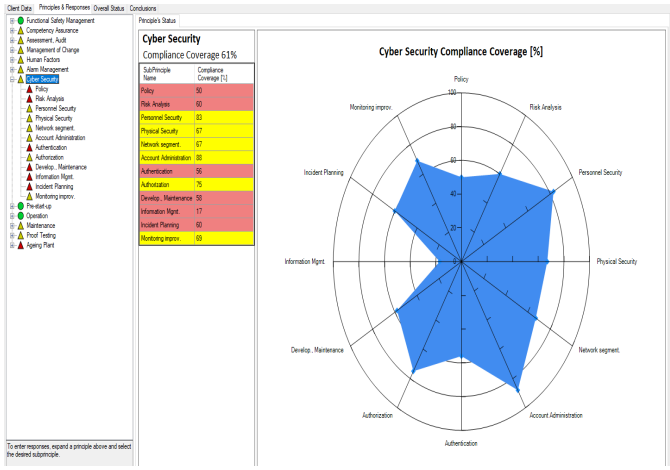

Figure 2 – Example Sub-principle FSA result for Cybersecurity

The opportunity to speedily set up trending and comparison of data for a single Asset or more than one Asset would be a desirable outcome for any reporting criteria. Such FSA Tool can provide scoring mechanism and compliance coverage graphics to aid comprehension of any key issues with budget holders regarding the improvement recommendations to be planned and implemented.

An example of how such information could be scored and weighted are as per figure 2:

VII. Conclusions

From experience, FSAs can reveal real errors and deficiencies in management processes, technical capabilities, and misalignment with the operating facility risk reduction requirements for installed operational safety related systems.

Such deficiencies can manifest themselves as issues such as:

- An insufficient independency between protection layers that are unrevealed and acknowledged during the process of safety function allocation to protection layers, thus leading to inappropriate safety requirements and required reliability measures
- Deviations in device safety manuals and by detailed review of supporting device certification reports, identification that installed devices do not meet safety standard requirements for use
- Management of change issues caused by a loss of system 'Freeze' for safety system modifications, leading to differing teams working on differing versions of system documentation and associated common safety function modification requirements
- Inadequate Hardware reliability calculation where too low failure rates used leads to too low PFDavg achieved and omission of compliance with Systematic Capability requirements, both leading to higher claimed SILs than in reality
- Lack of substance in change management 'Impact Assessments' leading to changes being approved that potentially compromise both safety functionality and safety integrity
- Safety system corrective maintenance that has evolved to a 'modification' without supporting impact assessment and document revision controls
- Real discrepancies and misunderstanding between Safety Instrumented Function (SIF) device response times and overall Process Safety Time (PST) leading to non-compliant PST claims
- Conflicting client requirements for both application program 'destruct' and 'construct' using the same field devices & I/O for differing SIF requirements
- Identification that safety devices are operating well outside the manufacturers 'useful life' requirements and continue in operation without justification or obsolesce planning
- Out of date safety case / dossier (including H&RA & SIL Determination reports and Safety Requirement Specifications) to that of the current plant process operating envelope
- *And many more….*

By contrast a robust FSA process can provide the operating company with the following benefits:

- Documented demonstration of senior management commitment and focus for continuous improvement
- A defined assessment and review process for supporting overall stage 4 periodic FSAs in accordance with IEC 61511 clause 5.2.6.1.10
- Demonstration that actions to ensure the process functional safety are being taken showing the pro-active attitude which is expected by the regulatory authorities, public and workforce, and supports company risk management arguments and traceability to industry good practices
- Knowing in advance from proactive assessment results, that prioritised improvement is required aids business planning and avoids 'surprises'
- Provides essential information on how to maintain the level of safety designed into the facility safety related systems
- Supporting effective barrier management to reducing the plant spurious trip rate and cost of its consequences
- Provides evidence to authorities and business insurers that normative requirements and good practice on safety related systems management can be presented in structured and logical way
- Allows the Asset Owner to highlight the areas in most need of improvement, whilst in some cases relaxing the demands on sparse operational resources by using a risk-based FSA approach
- Provides the Asset Owner with a means to benchmark differing operational assets to identify trending for both good practices and those areas that are not performing to expectations, thereby providing a common understanding for risk management across several business locations

So, in your organisation, where is your planning for undertaking periodic FSA? Who will conduct them, and what will be the scope of assessment?

To ignore undertaking this important FSA activity is to do so at your peril. From the author's experiences operating in various high hazard manufacturing operations over many years, any such ***'complacency invites increasing operational risk'.***

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IX. VITA

John Walkington has some 39 years' experience within the Process Industries working previously for operating companies such as ICI Agrochemicals, ICI Chemicals & Plastics, BASF Chemicals & Plastics and Huntsman Refining & Petrochemicals, before joining ABB in 2003. This is in addition to providing process and functional safety consultancy and training services directly to ABB's customers.

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