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Digital Transformation: Publication Style

By Renee Bassett, *InTech* Chief Editor

According to our most recent reader survey, if you're holding a tablet or phone, or using your desktop computer to read this article, you're a member of a digital majority. Sixty-seven percent of you report reading *InTech* magazine's digital edition, which has been coming to your inboxes for more than six years. Thirty-eight percent of you visit www.ISA.org/InTech to read there. In fact, 46 percent of readers never pick up a paper issue to skim through the ads and articles.

When we asked the question a different way, survey respondents told us the most important media formats for finding and reading professional material were websites (71 percent), ebooks (58 percent), and newsletters (52 percent), followed by print magazines (43 percent). We've seen the writing on the wall for a couple years now: Fewer of you every year hold paper copies of *InTech* to read them. At the same time, costs for paper, printing, and postage keep climbing, and calls for a more sustainable approach keep coming in.

It is with a bit of sadness but much gratitude for the benefits of digital publications that I say this is the last issue of *InTech* in print.

So, it is with a bit of sadness but much gratitude for the benefits of digital publications that I say this is the last issue of *InTech* in print. After years of pilot projects and deliberations, the digital transformation of *InTech* magazine is a reality.

As an industry consultant states in this issue's Executive Corner column, "Digital transformation is the process of intentionally bringing about comprehensive changes, after due deliberation, by leveraging emerging digital technologies to achieve overarching objectives."

Starting in 2023, this flagship publication of ISA—International Society of Automation will be published only in PDF format, six times per year. The *InTech FOCUS* ebook, which for the past couple of years has supplemented *InTech* magazine with a focus on fundamentals, will be folded into the *InTech* magazine ebook.

ISA members and other subject matter experts will continue to contribute articles that inform and educate. Article topics will continue to cover the range of ISA content categories, as well as provide news about ISA standards, certifications, trainings, and events. Starting with the February issue, a new all-digital format will be delivered instantly to thousands around the world—no postal delays or damaged copies. More links to additional resources will be included, and each issue will remain easily sharable.

Also coming in 2023, making the most of having no printed-page space constraints, is a new digital publication stream: InTech Whitepapers. Longer than magazine articles and shorter than books, InTech Whitepapers are single-topic, in-depth reports with citations. These will be distributed via existing ISA.org and Automation.com digital channels and will be online alongside *InTech* magazine ebooks.

I'd love for you to join us in our digital transformation. Sign up to receive your issues via email at https://www.isa.org/intech-home/subscribe. Share the QR code on the cover with new coworkers so they can sign up too. Submit your articles and whitepaper reports to InTechContent@ISA.org. And share your thoughts on what's in store for you in 2023. Is there digital transformation in your future? ■

InTech

OFFICIAL PUBLICATION OF THE INTERNATIONAL SOCIETY OF AUTOMATION

Digital Transformation: Evolution or Revolution?

By Jack Smith

Smith (jsmith@automation.com) is a contributing editor for Automation.com and ISA's *InTech* magazine. He has been a trade journalist for 22 years.

The manufacturing industry continues to be inundated with buzzwords. Automation, in particular, has its share of technical lingo. In the mid-2000s, the phrase shop-floor-to-top-floor was prevalent, as was enterprise connectivity and communication. What do analysts and marketers gravitate toward now? Industrial Internet of Things (IIoT), Industry 4.0, edge, cloud, and digital transformation are now fully part of automation vocabulary.

While much of the underlying technology is remarkably similar to that from 10 and 15 years ago, there are differences that must be acknowledged and understood. For example, the concept of connectivity is not new, but the potential for wisely using data obtained through the right connectivity is the objective to be pursued today.

Consider "digital transformation." Skeptics say the process is more like an evolution than a transformation. It is a journey and should be treated like one, because once you get "this" done, there is more to do. More innovations happen, more technologies that can solve problems are introduced, and there's always more to do.

So, is "digital transformation" an evolution or is it truly transformative? It's actually both. Digital technologies had to evolve to get from where they were to where they are now. On the other hand, when appropriately applied, those same technologies are transforming companies for the better. A smooth digital transformation journey relies on data in digital form, processes that are digitally managed, and the right data at the right time.

The concept of connectivity is not new. But the potential for wisely using data obtained through the right connectivity is the objective to be pursued.

It's a journey

In his article "Digital Transformation Strategy," https://www.automation.com/en-US/Articles/July-2021/Digital-Transformation-Strategy, consultant Rajabahadur V. Arcot says, "Digital transformation is the process of intentionally bringing about comprehensive changes, after due deliberation, by leveraging emerging digital technologies to achieve overarching objectives, which, in the business context, often includes improving a company's business, production, and operational processes."

Arcot also says that digital transformation is driven by the collection and use of data. Digital technologies like IIoT, edge and cloud computing, data analytics, and artificial intelligence are excellent tools for creating, collecting, and analyzing this data. He also says that data digitization and process digitalization are foundational to digital transformation.

"Digitization is the process of converting image, sound, document, etc., information into a digital format that can be processed by a computer. An example is the conversion of input signals from transmitters to a DCS [distributed control system] from analog signals to digital signals by using communication protocols such as Fieldbus," Arcot explains. "Digitalization refers to enabling or improving processes by leveraging digital technologies and digitized data."

What will they call it next?

Digital transformation means different things to different people and different companies. One company may be just starting its journey, while another is reaping major benefits because it is farther along the digital transformation path. Those who are successful approach it as a process of continuous improvement and refinement. "Continuous improvement," by the way, is more than just a buzzword borrowed from Lean manufacturing concepts. From a technological perspective, automation has always been a driving force for continuous improvement.

Arcot says a company that wants to launch a digital transformation program must ensure that the right data is in a digital format and that processes are digitally managed. If a manufacturer wants to achieve digital transformation, then it must have operational technology systems such as a DCS, programmable logic controllers, and/or a manufacturing execution system already in place. "Digitized data and digitally managed processes are prerequisites to move forward with any digital transformation program," he says.

Call it what you will—digital transformation or digital evolution—it needs to be done. What are you waiting for? ■


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Smart Gauging Systems Improve Tank Farm Efficiency

IIoT-ready instrumentation can quickly enable data-driven reductions in failures and downtime.

By Cesar Martinez

The second law of thermodynamics states the total entropy—or natural disorder—of any system increases or remains the same in a spontaneous process. This is a foundational facet, one of the building blocks of thermal physics at the molecular level, and regardless of debate among physicists, it almost always applies to visually tangible macrosystems as well.

This principle is arguably the strongest driver for control systems, given the whole point of control is to methodically manipulate inputs from an environment containing varying levels of disorder into specific outputs that bring about desirable outcomes. These points warrant the requirement of maintenance in every plant, because equipment naturally degrades over time. Mechanical components wear, electrical connections corrode, and even static objects degrade due to atmospheric contact, or exposure to chemicals and other hazardous conditions.

Putting a spotlight on tank farms, maintenance is necessary to ensure measurement accuracy and plant safety. Maintenance activities have evolved over the years, with new technology built into modern smart instruments, providing more methods to diagnose issues, share data, and verify measurement integrity.

Historically, these activities had to be conducted manually, requiring technicians to perform tasks in the field, often in hazardous conditions. But data-rich sensors and intuitive software solutions are making it much easier to identify and address problems, so plant personnel can improve their productivity while reducing downtime and incidents.

Inevitable breakdown

Degrading measurements in a plant can be thought of analogously as degrading fuel economy in an automobile. As a car racks up more miles, its engine and other mechanical components slowly wear down, requiring more fuel to drive the same distance, thereby decreasing fuel efficiency. This drop may be miniscule at first, but it can become more significant over time.

In the same way, measurement errors as instruments degrade in a plant environment may be small at first—often unnoticeably so—but as wear compounds, measurement drift increases. Additionally, as instruments age, there is a higher chance of complete failure.

In the past, maintenance teams performed service at routine intervals to reduce the effects of measurement drift, as well as the chances of total failure. But this sort of calendar-based maintenance strategy is inefficient, because some instruments may not need service at their appointed time, while others may fail before the maintenance interval. When the latter occurs, maintenance must be performed reactively and expensively, and downtime often ensues.

For tank gauging applications, reactive approaches frequently begin when a mass balance issue is realized. Troubleshooting these types of issues with traditional instrumentation can take inordinate amounts of time. Operators must visit each tank, making individual manual measurements to determine the source of the measurement errors. Once the issue is identified, often hours or even a day later, maintenance teams are called out to repair the problematic instruments.

Online diagnostics increase reliability and uptime

Today's smart instruments have a plethora of diagnostic data—one area of notable improvement over instruments of yesterday—and when combined with holistic tank gauging system solutions, operators can maintain their systems with much greater reliability. Instrument diagnostics and other functions make it easier to detect problems, with quicker troubleshooting and servicing when issues arise.

Centrally managed tank gauging systems provide a single repository for maintaining all components, including instruments, equipment, software, and maintenance devices. These systems can be easily connected to the cloud for enhanced monitoring and analysis solutions that generate insights, alerting maintenance teams of the ideal times to service instrumentation and equipment.

Using the software dashboard of these systems, operators can monitor field status at a glance, with anomaly and issue detection delivered via notification. When issues are detected, they are easier to troubleshoot because the system has predefined lists of error codes and descriptions, including cause and remedy. This can reduce the time spent troubleshooting and addressing issues in the field from hours to minutes.

Increasingly, these modern solutions are equipped with augmented reality (AR) capabilities. Field technicians put on a set of connected AR goggles, remotely projecting what they see to a support engineer. This engineer can reference diagrams and instructions on a computer in an office, and not only tell, but show, the technician which parts to adjust by using a virtual pencil tool to highlight the desired component, easing maintenance procedures significantly (figure 1).

But improved tools for addressing issues are not enough, as they need to be supplemented with diagnostics. In many cases, field devices sit untouched, without much idea of instrument health, until a process is disturbed, leading to unplanned, reactive maintenance activities. Using advanced tank gauging systems, personnel can access a history of events, current device status and health, and recommended remedies without spending any time at or on the tank (figure 2).

By connecting this local process, diagnostic, and event data to the cloud, advanced computing becomes possible, providing a health status asset dashboard and proactive maintenance insights. Using cloud connections and analysis

Figure 1. Using an augmented reality application, support engineers can see everything the technician sees in the field, and then guide troubleshooting or maintenance efforts using a virtual pencil to highlight target components for the technician.

engines, centralized software can observe patterns, create connections between historical input conditions and output results, and use these patterns to generate insights (figure 3).

Hardware, instrumentation, and communication configuration

A complete tank gauging system consists of instrumentation for measuring level and temperature and a scanner device in an electrical room to transmit data to a local or cloud-based information repository. Instruments must communicate via digital field protocols, such as HART, to send numerous diagnostic and process data points to the scanner device. A typical scanner can connect directly to a local database, or to an edge device, for uploading data to the cloud (figure 4).

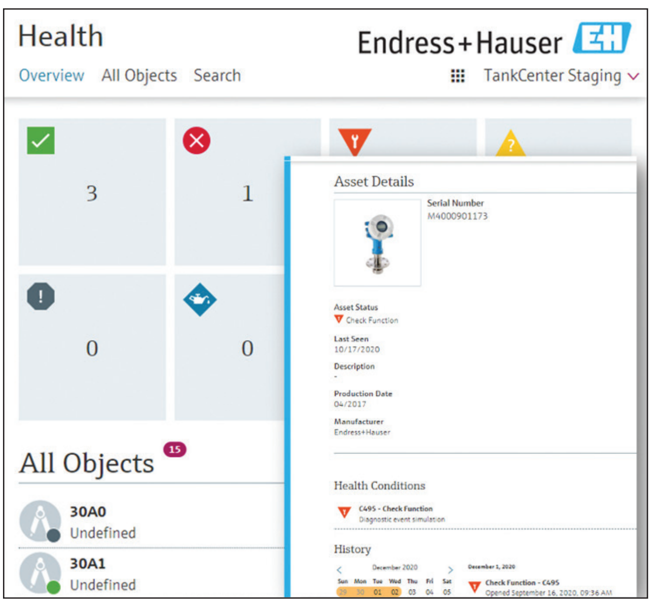


Figure 2. Dashboards and popups in an advanced tank gauging system provide an at-a-glance view of device health, event history, and other information.

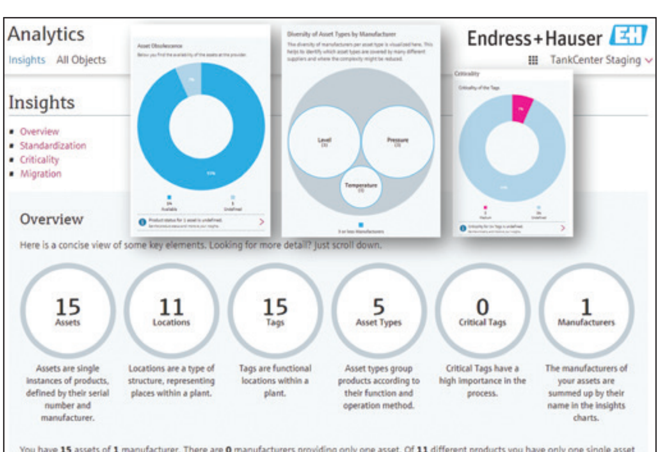


Figure 3. When connected to the cloud, users receive plant insights in the advanced tank gauging application.

Although asset information is often stored manually today, advanced tank gauging systems give users access to a cloud-based library for asset information by scanning a QR code on each device. The resources include the right user manuals (figure 5), associated product certificates, and instrument calibration information, with data uploaded at the time of automatic calibration procedures.

Outdated tank farm at a refinery

A refinery with a tank farm previously used traditional level sensors installed on top of the tanks. On multiple occasions, an allocation manager noticed a significant error during a product mass balance reconciliation. This required notifying operations staff and investigating further.

Operations personnel then verified levels in the storage tanks by performing manual dipping procedures, identifying differences in readings between the manual dips and the level sensor readings for each tank. Once this was done, they manually created a report of their findings, and sent this to the maintenance department.

Using this report, maintenance personnel created a work order in a disparate work management system, then sent specially trained staff to remediate the identified instrument issues. This frequently required multiple trips back and forth between the tank and the shop to exchange tools and consult user manuals.

Retrofit with a modern tank gauging solution

To reduce the effort required to identify, validate, and address these frequent problems, and to improve personnel safety and productivity, the refinery retrofitted its existing equipment using smart instruments and a liquid tank gauging solution. This provided a path to proactively address these sorts of issues with state-of-the-art Industrial Internet of Things (IIoT) technology.

The new level instrumentation came fitted with round-the-clock self-diagnostic capabilities with a connection to the liquid tank gauging solution health app. This app constantly monitors level sensor health, reporting the information to the dashboard and issuing alarms when anomalies are detected.

The refinery has had significantly fewer issues since the upgrade, but when anomalies or problems do arise, the system proactively identifies the issue without human intervention, automatically logging it and opening a work order in the connected computerized maintenance management system. It defines and categorizes the issue by device according to the NAMUR NE107 standard, and reports it immediately in the liquid tank gauging solution health app.

An alarm is sent to the maintenance department, and a technician logs in to the app to confirm the alarm and read the diagnostic information, including root cause, suggested remedy, and a link to the user manual. Alarm details are also provided, identifying the time the anomaly or problem was detected.

Fully informed of the context, the technician is empowered to grab the right tools the first time before venturing to the tank. And in the event specialized technical support is required, AR goggles provide a means for additional guidance from a remote technical expert with intimate knowledge of the system. This third-party support alleviates the need for the refinery to hire and retain highly technical talent.

Examining total cost of ownership

Frustration with the old instrumentation was not the only motivator for the previously mentioned refinery's system upgrade. It also studied total cost of ownership (TCO), a critical performance indicator for evaluating the benefit of tank gauging systems. Typically, about 20 percent of this cost is attributed to initial purchase and startup costs, and 80 percent is attributed to operational costs. Although purchase price cannot be overlooked, operational costs are typically much more consequential over the life of these systems.

TCO can be reduced by:

- standardizing with a tank gauging system
- enabling cloud connectivity for enhanced monitoring and insights
- implementing process and safety improvements
- reducing time spent on top of the tank
- eliminating obsolete equipment to reduce excess maintenance
- engaging third-party support to reduce in-house technical expertise requirements.

From thermodynamics to business continuity

The second law of thermodynamics is not exclusive to physics classrooms and textbooks. Left unmitigated, efficiency in any electrical, mechanical, chemical, or other industrial system inevitably decreases over time. The old world of tank gauging systems required extensive manual intervention to address issues and maintain measurement accuracy, but the next frontier automates most of these tasks.

Equipped with smart instrument features in a central repository—such as self-diagnostics, automatic calibration verification, and record keeping—along with the computing and alerting capabilities of the cloud, modern tank gauging systems are empowering plant personnel to move away from reactive firefighting to proactive and predictive maintenance methods. This helps maintain measurement accuracy, improves personnel safety, and increases system uptime, leading to fewer delays in transfer and distribution, and greater business continuity and reliability. ■

All figures courtesy of Endress+Hauser

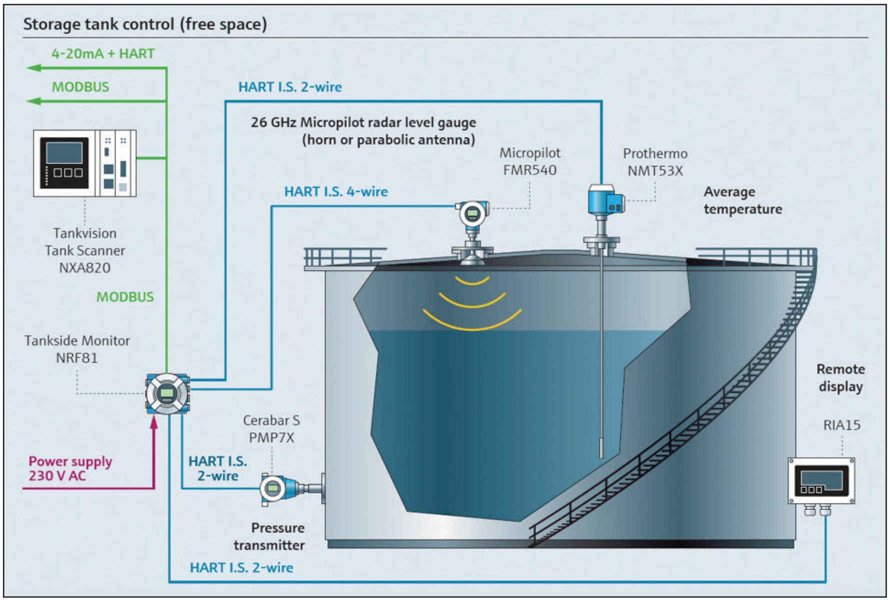


Figure 4. Example architecture for an advanced tank gauging system

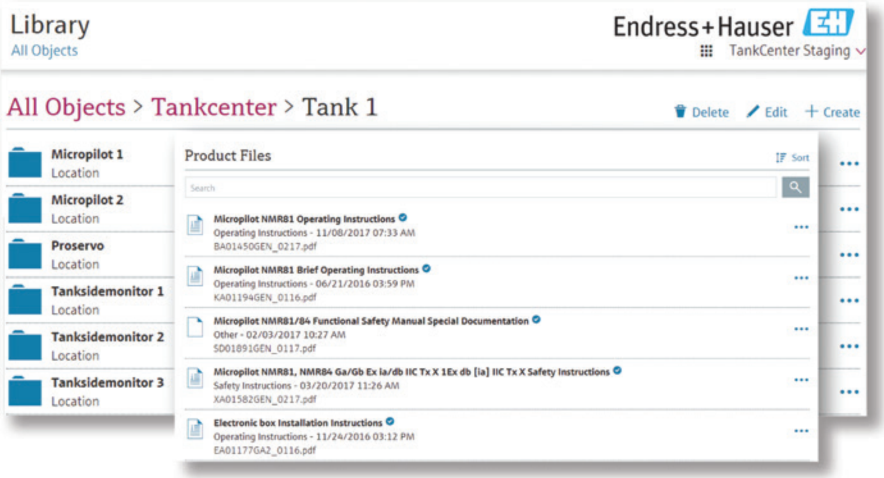


Figure 5. All relevant instrument documentation—including user manuals and calibration records—is automatically stored in an intuitive location in an advanced tank gauging application.

ABOUT THE AUTHOR

Cesar Martinez is an electronics engineer with more than 15 years of experience in the automation industry. He is passionate about automation, technology, digitalization, and energy transition topics. In his current role at Endress+Hauser, Martinez is the industry manager for natural gas, LNG, carbon capture, and blue hydrogen.

Defending Remote-Friendly Environments from Cyberattacks

By Damon Purvis

An oxymoron is a figure of speech combining two contradictory terms. When bidding a project, have you ever tried to create an "accurate estimate," or did your time off ever turn into a "working vacation"? In the context of secure remote access for industrial automation systems, some oxymorons like "friendly defense" or "open security" may come to mind.

Industrial remote access security is never achieved with a single plug-in appliance; instead it relies on layers of hardware, software, and procedural defenses.

Manufacturers and operating companies would like convenient access to their digital systems and production data, but they must take steps to mitigate the risk of cyberattackers stealing their data or disrupting operations. There are many complex technical steps and cumbersome procedural requirements these organizations can enact to secure their systems, but if these steps make gaining remote access impractical, then it will be impossible to realize value. Another issue arises for smaller organizations, especially those solely focused on their core competencies, that do not have enough resources for researching and applying cybersecurity measures.

In search of an answer, many companies hear and like the term "defense-in-depth," defined by the National Institute of Standards and Technology as an "information security strategy integrating people, technology, and operations capabilities to establish variable barriers across multiple layers and missions of the organization." But what does this mean for original equipment manufacturers, systems integrators, and end users looking for workable ways to implement secure remote access to their industrial systems?

Remote access, from a want to a need

Remote access for industrial automation systems generally involves connecting on-site operations technology (OT) assets like programmable logic controllers (PLCs) and human-machine interfaces (HMIs) to enterprise and information technology (IT) computing systems that are on site or in the cloud. This remote access can take on one or more forms:

- performing basic data transmission to a database or historian
- enabling remote and mobile visualization, which can include accessing a local HMI or populating data for a web-based dashboard, viewable on a PC or mobile device
- allowing operators to make set point and alarm limit changes
- supporting the upload/download of PLC programs, HMI configurations, and other network maintenance
- transmitting alarms and notifications, usually via text or email, and providing an acknowledgement method
- connecting with manufacturing execution systems and/or enterprise resource planning applications.

For many years, users wanted these features mostly for their convenience in the operation, optimization, and maintenance of their automated systems. Unfortunately, many types of automated equipment, especially smaller standalone systems, were "air-gapped" and not connected to any type of networking, so implementing remote access required a lot of custom engineering effort. Even when a system could be networked, many users simply did not have the expertise to establish remote connectivity, or if they did, they were rightfully concerned about cybersecurity.

However, the reality today—especially considering the COVID-19 pandemic—is that all types of users now require remote connectivity to fully engage their production, engineering, and maintenance teams, regardless of where they are located. Of course, an increasing prevalence of connected systems means that digitally controlled production environments become vulnerable to new risks, many of them directly associated with human error, negligence, or retaliation. There is no choice but to overcome both technical and security challenges to provide the remote accesses needed, but in a practical manner.

Layered defense

Defense-in-depth refers to a layered cybersecurity approach meant to defend against vulnerabilities that are inherent to digital and physical assets and the people who use them. Typical IT departments already have systems and policies in place incorporating these requirements. OT departments, on the other hand, are less likely to follow this approach, because OT products have typically offered few cybersecurity features, and cybersecurity was not a key focus for industrial systems until the rise of connectivity options in recent years.

With this in mind, what topics should be considered as an organization develops a defense-in-depth strategy for remote access of industrial automation assets? Following are key concepts for properly applying security measures that will satisfy both OT and IT.

OT/IT convergence. As industrial automation hardware and software have been adapting commercial networking technologies to a greater extent, instead of using dedicated or proprietary methods, the OT and IT domains have been converging. OT houses the source assets requiring connectivity, but IT is almost always required to establish connectivity to on-site networking and the Internet. Even if a cellular or satellite technology is used, the IT group typically will be called upon to apply its security policies.

Many IT groups warily view the OT arena as the "Wild West," where keeping things up and running is paramount, regardless of policies and procedures. Conversely, OT groups have found that IT personnel can be overly restrictive and even paranoid in their pursuit of comprehensive security. Therefore, it is essential for success that both OT and IT groups work together consistently, and not just to tie up loose ends at the conclusion of a project (figure 1). Cybersecurity must instead be designed and built in from cradle to production, with shortcuts or bypasses strictly avoided.

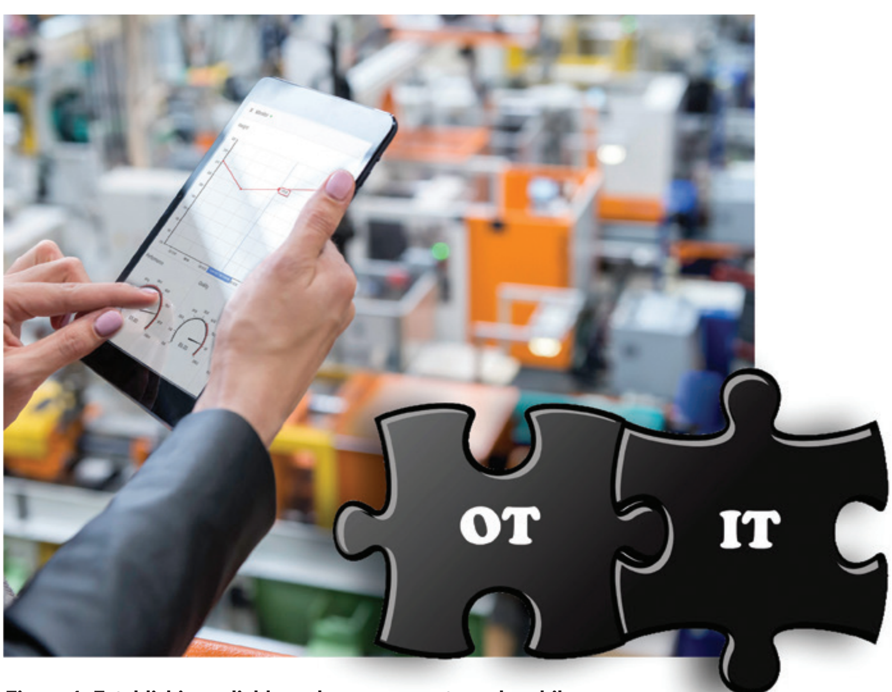
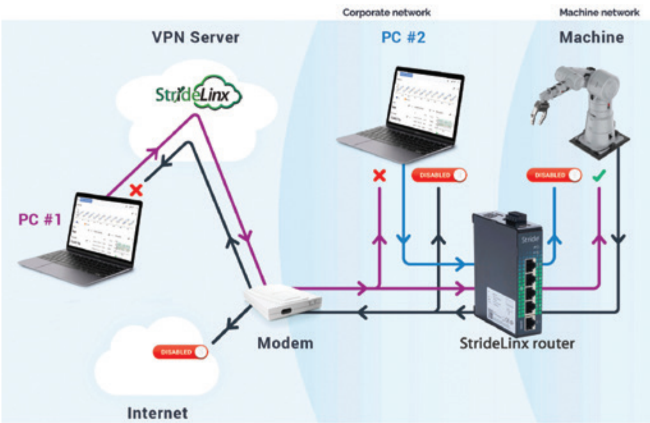


Figure 1. Establishing reliable and secure remote and mobile access for industrial automation systems requires OT and IT groups to work together, from project inception through production.



From		To	Mode	Accessible?
PC #1	>	Machine	VPN	✓
PC #1	>	PC #2	VPN	✗
PC #2	>	Machine	TCP	DISABLED (1)
Machine	>	PC #2	TCP	DISABLED (1)
Machine	>	Internet	TCP	DISABLED (1)
Machine	>	PC #1	VPN	✗

Figure 2. A comprehensive VPN and remote connectivity solution includes methods for OT assets to integrate with IT infrastructure for user management, authentication, and access control.

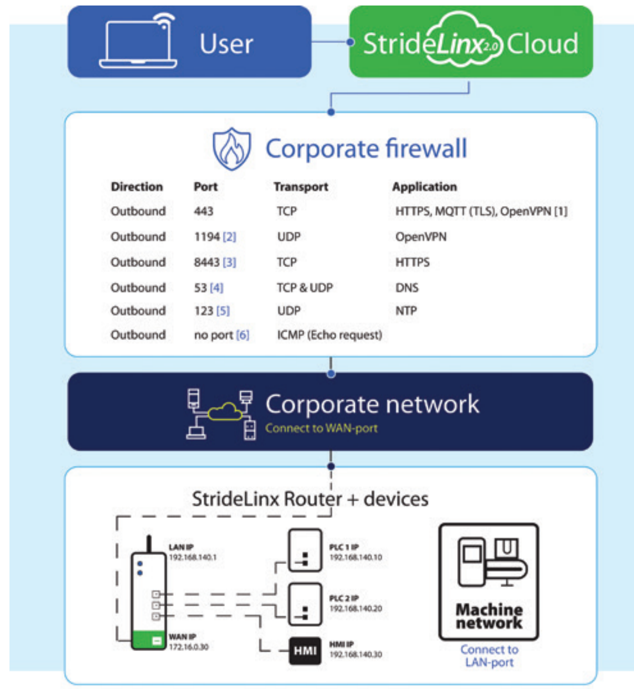


Figure 3. Trustworthy remote and mobile access providers will be prepared to work with industrial OT and IT groups to define the location and characteristics of all hardware, software, and networking architectures.

Technology selection. Working cooperatively, OT personnel should consider the remote access technologies that IT recommends, supports, and recognizes as secure. The number one answer is typically a virtual private network (VPN) solution. VPNs extend a protected network connection between two or more endpoints over open or public networks. VPNs encrypt all traffic and obfuscate device IP addresses, making it difficult for third parties to access or interfere with the data.

Most IT departments will accept VPN technology, but more rigorous organizations may require the OT group and/or a VPN provider to complete a checklist before implementation. Reputable VPN hardware, software, and services providers will help with this process. Users are advised to avoid providers that fail to supply clear responses, or those lacking verifiable documentation and certifications.

User management and authentication. Most IT groups employ user authentication controls to manage user access. Authentication confirms that users who log in—whether locally or via a public network—are who they say they are, and authentication in turn provides a way of granting appropriate access (figure 2). Traditional OT systems most often provided open access, because older technologies did not include significant security features, and in any case the industrial user was typically most concerned with *availability*, at the expense of *confidentiality* and *integrity*.

Modern OT products are now more likely to incorporate authentication provisions compatible with and acceptable to the IT infrastructure. Single sign-on (SSO) is an example of a technology that seamlessly integrates with Microsoft Azure Active Directory and Google's OAuth 2.0 application programming interfaces (APIs). The IT group may take additional steps, such as enabling multifactor authentication—which requires additional user input such as a PIN code, possession of a security USB stick, or use of an authenticator app—for an additional layer of protection.

Defense-in-depth refers to a layered cybersecurity approach meant to defend against vulnerabilities that are inherent to digital and physical assets and the people who use them.

Architecture. A trustworthy VPN and cybersecurity service provider, whether it is OT- or IT-centric, should be able to provide documentation about the architecture, so all parties

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can make informed decisions about the implementation. There are usually on-premise, cloud, and hybrid options and aspects for architectures (figure 3). Servers, firewalls, and other devices are needed, so all parties need to understand where these will be physically located, and who will manage and maintain them.

Some solutions rely on external resources delivered as infrastructure-, platform-, and/or software as a service (IaaS, PaaS, SaaS), and each of these resources needs to be vetted. Any solution using the cloud will likely be associated with one or more cloud providers, each of which must be examined for digital and even physical security.

As part of this vetting process, these and other questions must be answered satisfactorily:

- Are data centers local or international, and are they located strategically to provide minimum latency and maximum uptime?
- Does the provider offer a service level agreement, so that end users can be assured of the quality and availability of the connection?
- What OT and IT assets, such as firewalls, will need to be configured to integrate within the architecture? How do you securely configure these to be as strict as possible?
- Is the provider familiar with the OT assets providing the data, and the IT tools required to ensure cybersecurity and compliance?
- How much customization is required for a working solution? Does the customization comprise the overall security of the solution?

Once these questions have been answered, it is time to proceed to the next step.

Implementing a complete and secure remote access system

The preceding sections might seem to raise more questions than answers, which is understandable because implementing a complete and secure remote access system is not as simple as buying an appliance and plugging it in. Some OT and IT groups may be able to create such a system from scratch, or using various products, but creating a comprehensive, demonstrably secure, and maintainable solution is a complex challenge.

A better approach is to build on an established commercial off-the-shelf solution backed by an experienced industry supplier. A dependable provider will have educational and specification assets in the form of white papers, network architecture drawings, videos, and other online support resources. The provider will include free phone support, along with assistance for addressing all OT and IT security concerns.

VPN solutions will integrate OT assets with IT infrastructure, using SSO and other technologies. Cloud resources will consist of dozens of servers distributed worldwide—for segmentation and stability reasons—with endpoints close to user locations and 24/7 security monitoring. Last but not least, users should look for solutions certified according to ISO 27001, which addresses information security management, to verify the highest standards are upheld.

Suppliers offering these types of services will provide the assistance required for organizations to implement and support secure remote access. In most cases, the cost of engaging competent suppliers is less than hiring and retaining sufficient internal staff, creating a mutually beneficial relationship that makes financial and technical sense. ■

All figures courtesy of AutomationDirect

ABOUT THE AUTHOR

Damon Purvis is the PLC product manager at AutomationDirect.com. He has more than 22 years of industrial automation experience. His previous roles include designing and deploying automated solutions in a variety of industries and managing product development of manufacturing data management and business intelligence applications.

Standardized Foundation, Faster Development Pipeline

By Kristel Biehler

The life sciences industry is changing quickly, and in the past five years, the pressure to bring new treatments rapidly and safely to market has increased dramatically. In 2021 alone, life sciences manufacturers initiated more than 25,000 new clinical trials. But to take those clinical trials to successful production can take many years—a timeline that is no longer sustainable. A perfect example of this shift is the development of the COVID-19 vaccine.

Life sciences manufacturers speed time to market with MES and knowledge management software.

Life sciences manufacturers were able to reduce the schedule for COVID vaccine development through emergency authorizations and by committing billions of dollars and thousands of people to the development process. However, COVID vaccine development was a unique situation. Not every treatment is going to receive the attention and investment necessary to shorten the production pipeline so dramatically. Ultimately, life sciences organizations need to look to other methods to shorten time to market, and one of the most important technologies for doing this is the manufacturing execution system (MES).

But driving speed in the manufacturing stage of treatment development is not enough, because life sciences organizations need to accelerate the entire development pipeline. By using modern software solutions to hasten technology transfer, and then leveraging the advantages of a robust MES, teams can fully capture the competitive advantage of speed to market.

Seeing the development pipeline holistically

Today, technology transfer often moves slowly due to barriers created by silos across the drug development pipeline. In the worst case, critical data stored on paper and in spreadsheets is difficult to move from stage to stage, and it is subject to loss and error. Records, recipes, and other critical data must be reorganized at each stage—a time-consuming and frustrating task, and one prone to error. But even in the best case, different groups along the production pipeline typically use different software packages, different databases, and even different production scale and language, which slows the transmission of data from one stage of development to the next.

Overcoming these hurdles means rethinking the traditional ways teams approach technology transfer. The best MES technologies offer simpler integration to help manufacturing teams more easily use the data they receive from research and development, but this is only one element of treatment design and manufacture. Benefitting from speed to market also requires quickly moving treatments through the development pipeline by improving technology transfer at every stage, a problem that can only be solved by standardizing the way each group interacts within the development chain.

Much like the move from paper records to digital, the MES has digitalized the manufacturing portion of the treatment development pipeline.

Digitized data is a start

Some development pipeline standardization has already occurred. Few modern life sciences manufacturers are still maintaining handwritten documentation. Most instead opt for electronic records, which has inherently reduced much of the variability between groups. Digitized records are a must, not only to speed the processes of research, development, and manufacturing, but also to streamline release and compliance. But in many cases, the digitization of records means teams have begun using electronic spreadsheets to record data, or they are using proprietary applications for their specific area of treatment design and manufacture.

Although the move to digital spreadsheets from paper records improves the technology transfer process, it still frequently leaves different teams inadvertently creating silos of data that are difficult to move along the pipeline. Scientists in preliminary research often use different tools from those in clinical trials, who, in turn, use different tools than the manufacturing personnel. Activities performed, insights gained, and aberrations remedied are difficult for teams further down the pipeline to access and assess.

This difficulty arises because moving data often means transferring it from one application to another. Such a transfer may require rebuilding or reformatting a database. In other instances, connecting two systems together may require a custom architecture that is complex to create and difficult to maintain. If the person who created that custom solution leaves the organization, the knowledge for maintaining that system goes with him or her, and the process must begin again, further delaying progress.

A new tool for the digital age

To circumvent these barriers to rapid technology transfer, forward-thinking teams are using software technologies to break down the silos between groups in the development pipeline. These teams use process and knowledge management (PKM) software to standardize information transfer across the entire development process.

PKM software creates an electronic repository to capture every decision made across product development, speeding the whole pipeline—from research to commercial production—and potentially reducing the technology transfer timeline from years to weeks. All personnel have access to the information they need using a standardized set of web-based tools with an intuitive drag-and-drop user interface. The simplified interface standardizes the creation of products and processes. Teams can more easily conform to ISA standards, for example the ISA88 series of standards, and can more easily locate, share, and comprehend information at any stage in the cycle.

The most advanced PKM systems also natively integrate with other critical systems, such as enterprise resource planning, electronic lab notebooks, laboratory information management systems, the distributed control system (DCS), and the MES to offer far greater visibility, scalability, and collaboration among cross-functional teams. With standardization via built-in templates, teams can more easily use common definitions and keep them up to date over time, even pushing changes to multiple recipes simultaneously to save hours of manual data entry. In addition, with automated change tracking, teams no longer need to worry that changes in products and processes will create compliance issues. Built-in auditing tools make it easy to track, monitor, and confirm changes.

PKM software also provides a structured, configuration-driven approach to help cross-functional teams manage process parameters and calculations, without an external electronic spreadsheet application, because all activities can be performed directly within the software. PKM software also can conduct facility-fit scenarios using predictive algorithms to easily identify production gaps through exception reporting.

More effective manufacturing execution

PKM software also helps close the gap between research and development and the MES, a critical tool for speeding commercial production. Much like the move from paper records to digital, the MES has digitalized the manufacturing portion of the treatment development pipeline. MES software increases

Figure 1. Built-in workflows in MES software help ensure every task in the manufacturing process is performed correctly.

visibility of life sciences manufacturing operations to eliminate the inefficient use of resources, and to streamline communication and collaboration in full-scale production.

Standardized batch records, efficient exception management, improved consistency, and facility-wide equipment management built into the MES help manufacturing teams build an automated workflow to better manage procedures, equipment, materials, and quality. In addition, integrated workflows help ensure that production is reliable and repeatable (figure 1).

Modern MES software also eliminates the need for customized integration to the DCS. Instead, high-performing MES software natively integrates with the DCS, removing common challenges with data integrity and system performance.

These MES benefits significantly streamline production, helping to speed return on investment and shorten time to market. To capture the most benefit from these advantages, however, teams must close the most difficult technology transfer gap: the handoff from development to the MES.

Standardizing across the gap

Development and manufacturing typically use different systems and equipment, at entirely different scales. Making the move from development to production means transferring all the data necessary to the MES and scaling processes up from bench- to production-scale equipment. Fortunately, PKM software seamlessly interfaces with high-performing MES software.

These fit-for-purpose PKM solutions make it easier to transfer master recipes. The recipe repository is directly linked to the MES, eliminating the need for conversion or for custom—and fragile—connectivity between the two systems. The PKM system can seamlessly push parameters and sequence of operation to the MES, helping teams better manage inventory, while providing improved visibility of manufacturing guidelines. Experts estimate this type of connectivity can help reduce time to market from 10 years to fewer than three (figure 2).

Also, PKM software gives manufacturing teams visibility into the design process to help remedy any problems that may arise after a treatment is released to the market. Teams have

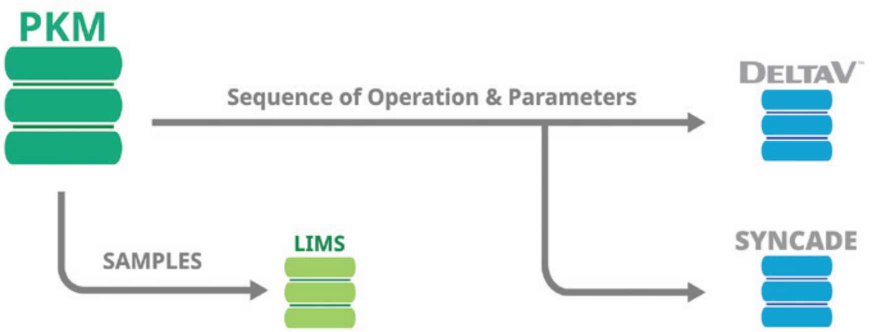


Figure 2. PKM software seamlessly integrates with the DCS to help shorten the most complex and time-consuming technology transfer stage—from R&D to manufacturing.

immediate access to data across the lifecycle of the product, providing both decision support and the required comprehensive data and audit trails to back up those decisions.

A robust MES supported by PKM software across the entire development pipeline can shave years off treatment development.

Meeting today's challenges with today's technology

There are more new life sciences products in development daily, making it harder to develop a treatment that will stand out among the crowd. In addition, the first product to market in each class typically becomes the market leader, increasing pressure on development teams that are already stretched thin.

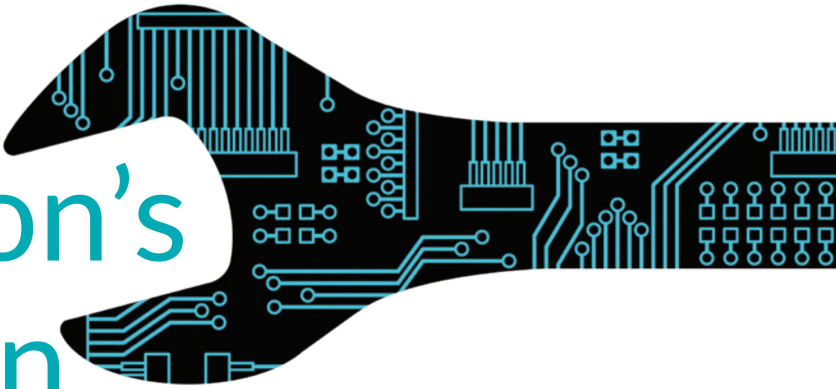
Although throwing money and excess staff at the problem can increase speed, most organizations cannot do so, because the pressure on therapy pricing continues to increase. A better solution is focusing on eliminating operational inefficiencies and improving technology transfer to bring products to market more quickly and effectively.

The technologies needed to eliminate inefficiency are already on the market. A robust MES supported by PKM software across the entire development pipeline can shave years off treatment development, while eliminating costly mistakes. The life science leaders of tomorrow are already embracing these technologies, and the investment is returned faster than many of them imagined. ■

All images courtesy of Emerson

ABOUT THE AUTHOR

Kristel Biehler is vice president of life sciences for Emerson's process systems and solutions business, where she leads the day-to-day business activities in sales, operations, and technology that serve the life science industries. In her previous role at Emerson, she was the automation solutions vice president of sales for the western U.S., where she led teams that helped customers identify, architect, and implement automation and digital strategies. Biehler started her career with Emerson in 1998, and she has a BS in mechanical engineering from the University of Utah. Before Emerson, she worked for Sorex Medical as an automation engineer.



Digitalization's Influence on Maintenance Strategies

By Allison Buenemann

Historically, process manufacturers lacked sufficient data to predict critical equipment failures and instead relied on reactive maintenance to get plants back online quickly following failure. Prolonged periods of downtime piled up costs, exacerbated by extensive manual troubleshooting and root cause analysis.

Today, a significant increase in digitalization and Industrial Internet of Things (IIoT) implementations is expanding manufacturers' access to equipment data, shifting the challenge from data availability to insight availability, and conversion of these insights into actionability. Process manufacturing companies are using

Leveraging algorithms and past performance, IIoT and analytics help determine schedules and increase uptime.

advanced analytics solutions to gain insights from their data to predict equipment issues and inform optimized maintenance activities, leading to proactive maintenance programs, higher equipment reliability, and reduced maintenance and lost production costs.

Data-driven maintenance

Maintenance strategies have evolved as more data is measured, stored, and made available than ever before. This wealth of accessible data lets maintenance teams predict failures, calculate trigger points for condition-based maintenance, and share these insights with the personnel on the frontlines who are scheduling and executing the activities.

As data-driven strategies increasingly replace time-based maintenance, manufacturers are cutting operational expenditures previously dedicated to maintaining equipment on an arbitrary preventive maintenance (PM) schedule. This approach is coming merely decades after time-based PM replaced historic run-to-failure approaches, which forced companies to shoulder many costly unplanned outages.

With digitalization and IIoT implementations, manufacturers now have access to the data necessary for optimal equipment maintenance and reliability improvements, but the challenge has shifted to creating the right environment for analytics where contextual data can be viewed alongside process sensor data, and where time-series-specific calculations can be easily applied by process subject matter experts (SMEs). Advanced analytics software applications address this and other issues, empowering maintenance and reliability teams to uncover insights from many sources of information, informing actions based on predictive and prescriptive analytics.

Data analytics in context

"Analytics" is a broad-brush term used to describe any process that uses math to turn data into actionable information. It provides insights into consumer behaviors, marketing effectiveness, supply chain agility, financial performance, and other business functions. "Big data" analytics are necessary to deal with data in large volumes, velocities, and varieties, and there is no data of larger volume, greater velocity, or higher variance than those collected by sensors in process manufacturing.

A typical process plant stores time-series data from sensors measuring temperature, pressure, level, flow, vibration, and much more. A single refinery, for example, can possess hundreds of thousands of sensors with samples—timestamp and value pairs—recorded on intervals of hours, minutes, seconds, or even fractions of seconds. When dealing with large multinational companies, the number of sensors enterprise-wide can quickly approach a ten-digit figure. Performing analytics efficiently among these vast volumes of data quickly becomes paramount to unlocking the value hidden within.

But using advanced analytics applications to create meaningful insights from oceans of data has prerequisites. Big data is inherently complex, and it must be thoroughly understood and cleansed before it can be used in modeling and multivariate calculations. And of course, the adage "garbage in, garbage out" also applies, so process manufacturers must ensure the integrity of their data collection and storage systems before venturing anywhere near advanced analytics.

Once process manufacturers begin shopping around, they will notice nearly every software product, platform, and cloud service on the market claims to perform some sort of data analytics, with the type of analytics performed differing based on each tool's intended functionality. The qualifier "advanced" typically refers to the use of statistics and machine learning innovations in analytics to assess and improve insights. "Augmented" analytics tap into the same innovation themes, while putting the analytics in the context of user business intelligence applications and other frequently used tools.

Decoding time-based analytics

Under the umbrella of advanced analytics, there exists a hierarchy, beginning with retrospective functions—including "descriptive" summary statistics and "diagnostic" root cause investigations—and building up to futuristic flavors like "predictive," which tells users when to act and "prescriptive," which instructs them what to do (figure 1). These various types of increasingly complex—and useful—analytics work together, with the former two informing the latter two.

For example, retrospective analytics focus on historical degradation rates, the impacts of running different products or operating states, and the measurement of known failure

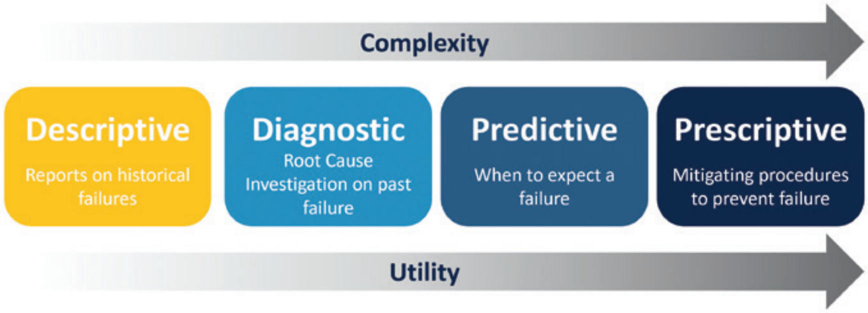


Figure 1. As analytic approaches progress from descriptive (retrospective) to prescriptive (proactive), they build on each other to increase in complexity and utility.

modes. By contrast, futuristic—or proactive—analytics spotlight the likelihood of failures, prioritization of maintenance, and other mitigating measures to reduce risk. Embedding these four types of analytics into daily operation leads to greater organizational analytics sophistication, and this act typically delivers quick return on investment by optimizing maintenance schedules and minimizing unplanned outages.

Many process manufacturers already possess a strong foundation in descriptive and diagnostic analytics, which are key building blocks for aspirational predictive and prescriptive analytics. By leveraging these fundamentals, engineers and data scientists equip themselves for the deep dive into high-value predictive and prescriptive analytics.

When it comes to maintenance planning and scheduling, combinations of retrospective and forward-facing analytics are needed to reach an optimal state. Knowing when components failed in the past, how and why they failed, and what was happening in the time periods surrounding these failures are all critical pieces of information required to predict future failures and prescribe effective mitigating actions.

Informing condition-based maintenance

Condition-based maintenance (CBM) was the idyllic maintenance strategy of the Lean Six Sigma age. The premise of CBM is that an event, trigger, or exceedance drives maintenance, rather than a schedule. The challenge with CBM was never in defining the condition that prompted a maintenance activity, because these conditions are often predefined by ancillary equipment constraints, like a maximum allowable temperature or pressure, or a minimum flow requirement. Rather, the challenge was in determining which limit would be exceeded, and when.

CBM is much more valuable when combined with model construction, marrying monitoring and forecasting techniques that together make up predictive analytics. For example, using near-real-time vibration data to do CBM on a fleet of pumps requires setting conservative triggers to effectively avoid running to failure in the time it takes to schedule and perform maintenance activities following detection. The downside of a conservative trigger is the inevitable presence of occasional false positives.

By contrast, when past and current vibration data is leveraged using a model, the model can construct a vibration forecast and compare it with historical runs in relation to other process signals. This better-informed prediction can approximate not only when a trigger will be hit, but when the failure is likely to occur, providing the greatest possible lead time for maintenance. In addition, these predictions can actively adjust over time, informing and updating the urgency of service based on how operation continues.

Digitalization-enhanced predictive analytics examples

Many manufacturers in the chemical and other process industries have transformed their operations by developing maintenance strategies built on the foundation of predictive analytics. As a result, these companies are minimizing downtime, unnecessary maintenance, and operational uncertainty,

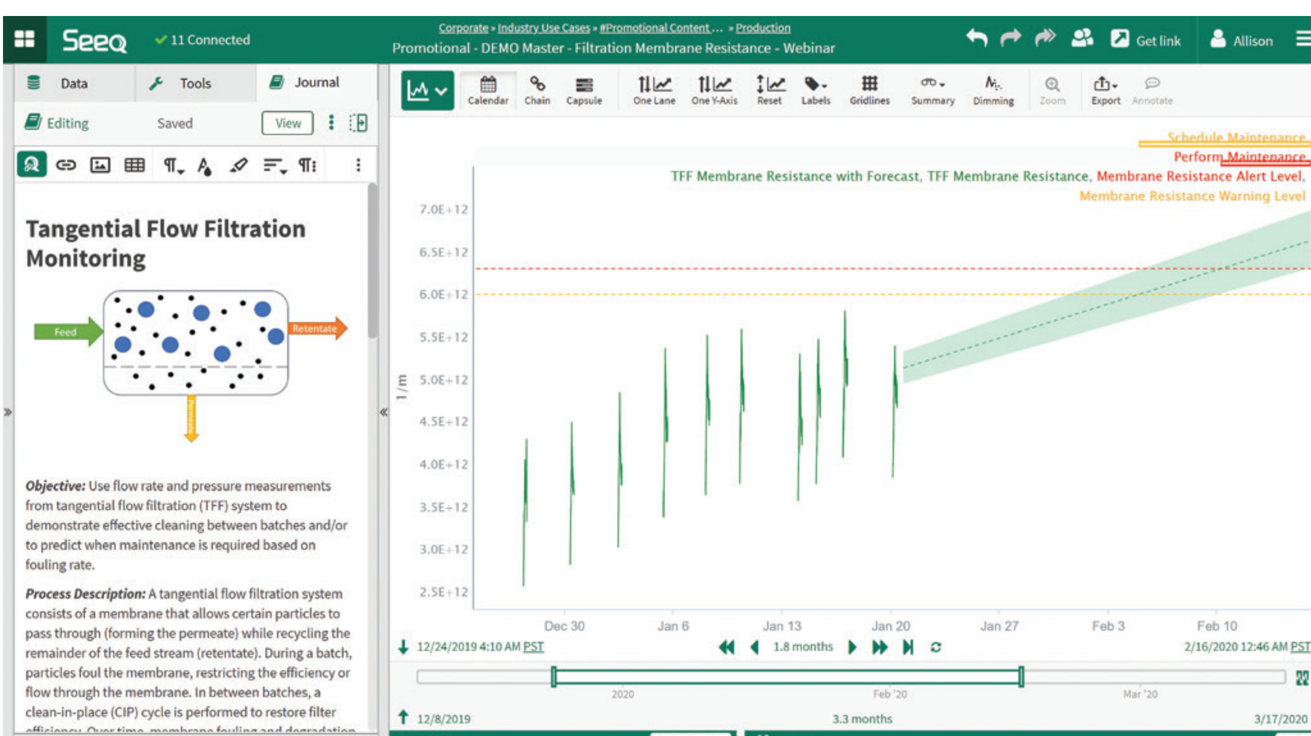


Figure 2. Data from multiple filtration membrane sensors was dimensionally reduced to establish a membrane resistance soft sensor in the advanced analytics application. The soft sensor was regressed and projected into the future to determine the appropriate maintenance date.

saving millions of dollars every year. The most successful predictive analytics applications often combine first principles models with statistical techniques to develop forecasts based on theory and behavior.

Filtration membrane predictive maintenance

When producing certain biopharmaceutical compounds, the desired molecules are separated from other species using membrane filtration systems. During each batch, particles build up on the membrane, and a clean-in-place (CIP) procedure must remove the accumulation between batches. Over time, these filtration membranes can degrade, causing CIP procedures to become less effective.

Engineers at a major bioprocessor suspected this was the case with one of their operations. Fearing unplanned downtime, they sought a way to identify long-term particle buildup on the permeate filter to predict when maintenance was required.

Using an advanced analytics application, the manufacturer calculated the filter membrane resistance based on pressure and flow sensor data, and on known values of surface and fluid viscosity, by applying Darcy's Law. This reduced the variables of interest, providing clear visual indicators of degrading membrane performance, confirming the engineers' suspicions (figure 2).

The team applied a linear regression algorithm to the data, effectively modeling the filtration degradation rate. This model was extrapolated into the future to build a predictive maintenance forecast and warning schedule, and maintenance activities are now proactively planned, maximizing the lifespan of filters and streamlining operations.

Catalyst end-of-run prediction

Degradation also occurs in the fixed bed catalysts used in hydrodesulfurization (HDS) units over time, requiring maintenance to avoid product quality issues that constrain allowable production rates. Engineers often use the weighted average bed temperature (WABT) as a key metric to determine catalyst bed health. However, other process variables—especially variable composition and flow rate—make it challenging to develop an accurate model of the WABT. For this reason, data scientists must cleanse and normalize calculated WABT values to create an acceptable data set for a regression model algorithm prior to plotting (figure 3).

To determine whether the degradation of the catalyst bed on an HDS unit had accelerated, engineers at a large downstream petrochemical company calculated and extrapolated multiple regression models to predict the required maintenance date. It became clear, after analysis, that the degradation rate had become more aggressive in recent months, and the HDS unit required an early catalyst change. Catching this issue early eliminated months of constrained-rate operation, saving the company more than $5 million in productivity losses.

Product run-length optimization

Fouling, catalyst degradation, and other process effects often constrain production rates throughout the course of a product

Figure 3. Using the advanced analytics application, SMEs compared WABT predictions from a full data set to a recent sample to determine maintenance requirements in the coming months.

run. This is frequently the case for polymer production processes where produced materials begin to coat the insides of vessels and pipes, restricting flow, building up pressure, and diminishing heat transfer. To remove such contaminants, manufacturers are forced to shut down and perform equipment maintenance, or execute online procedures, applying heat to coated equipment to melt off foulant layers.

A large polyethylene producer was experiencing production rate degradation due to the buildup of polymer skins on the walls of a tubular reactor, which restricted flow and increased the pressure delta, causing the process to approach the design limits of upstream equipment. The company sought a defouling strategy to increase production, prevent damage, and fulfill customer orders more quickly.

Using the advanced analytics application, a team of SMEs created a regression model of the degrading production rate to forecast when the production target would be met if no action were taken. They then compared this date to an alternative model incorporating multiple defouling procedures over the run. The team performed calculations to determine the optimal number of defoul cycles, minimizing the total time needed to produce a given order size.

Once the magic number was determined, the SMEs identified the appropriate minimum throughput rate trigger, and created a golden profile for the optimal number of future cycles between defouling procedures. This golden profile was formed from data collected during an optimal performance run, and it is used to continuously monitor and compare future runs as new data is recorded.

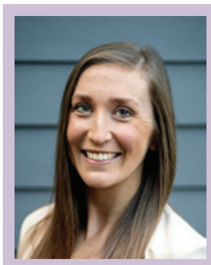
By deploying this model and performing analysis in the advanced analytics application environment, SMEs compared actual performance against the forecast to pinpoint the ideal times for executing defoul procedures. Implementing this model-based defouling strategy enabled a sold-out production unit to meet customer orders an average of 11 percent sooner over the course of the following year, empowering the company to grow market and profit share in its core markets.

Scaled predictive analytics enhance production

Just like in the academic lab, accurate predictions for process manufacturing operations depend on in-depth knowledge of past equipment behavior and outcomes. By using advanced analytics applications combining retrospective with proactive analytics, process experts and data analysts can easily build robust models capable of predicting plant maintenance needs and risk-mitigating procedures.

With collaboration among process, maintenance, and reliability experts, and with the right tools in their digitalization toolbox, process manufacturers can build better models and provide operations personnel with vast plant insights. Empowered with self-service analytics, staff can predict equipment issues well in advance of failure, helping optimize maintenance schedules and prevent costly downtime. ■

All images courtesy of Seeq



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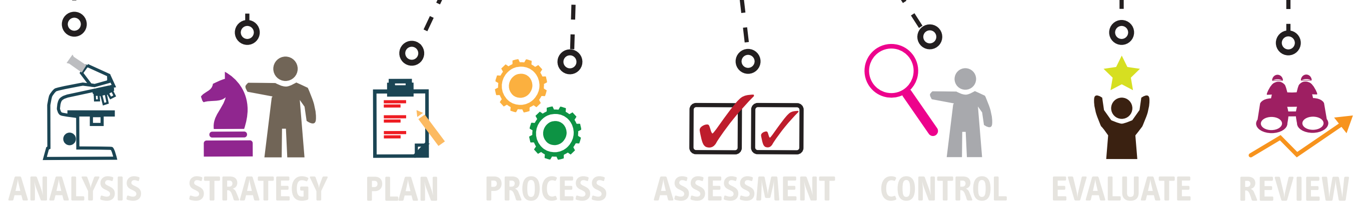
Allison Buenemann is an industry principal at Seeq Corporation. She has a process engineering background with a BS in chemical engineering from Purdue University and an MBA from Louisiana State University. Buenemann has nearly a decade of experience working for and with chemical manufacturers to solve high-value business problems using time series data. As a senior analytics engineer with Seeq, she used her process engineering experience to aid in new customer acquisition, use case development, and enterprise adoption. In her current role, she enjoys monitoring the rapidly changing trends surrounding digital transformation in the chemical industry and translating them into product requirements for Seeq.

Creating a LOPA Project Report



By Narasimha Himakuntala

LOPA reviews are intended to determine if there are adequate protective devices or features in the process to provide tolerable risk.

Layer of protection analysis (LOPA) is a method of analyzing the likelihood (frequency) of an event with a harmful outcome based on the initiating event frequency and the probability of failure of a series of independent protection layers, which could prevent the harmful outcome.

LOPA is one of the most used risk assessment techniques, and, in its simplified form, is only a semiquantitative technique. As with most risk assessment techniques, the primary focus of a LOPA review is to determine if there are adequate protective devices or features in the process to provide tolerable risk.

Protection layers are the most critical and fundamental aspect in any LOPA review. Most of the analysis is spent determining if the safeguards proposed by a hazard identification team can be independent protective layers (IPLs). In the hazard identification review, all safeguards are listed, and no estimations are made regarding their effectiveness in preventing the hazard or their dependence on one another. In the field, some teams assume certain safeguards can provide significantly more risk reduction than their true capability. LOPA resolves this problem by requiring the safeguards to meet predefined criteria before they are assumed to provide risk reduction.

LOPA methodologies

There are qualitative and quantitative LOPA methodologies. The qualitative LOPA methodology is performed one scenario at a time. The benefit of qualitative LOPA is it consumes less time and fewer resources than more quantitative risk analysis techniques. It also provides a consistent and defensible methodology for a company's risk and safety integrity level (SIL) target selection decisions. The steps are:

1. Identify all scenarios to be analyzed.
2. Select a scenario to analyze.
3. Estimate initiating event frequency.
4. Estimate consequence severity.
5. Determine the fully unmitigated risks.
6. Determine if the fully unmitigated risk is tolerable.
7. Identify the IPLs.
8. Identify the enabling conditions and conditional modifiers.
9. Determine the intermediate event frequency.
10. Determine if the risk is tolerable.
11. Determine how to provide the additional risk reduction, if needed.
12. Assign the SILs to safety instrumented functions (SIFs), if applicable.
13. Repeat steps 2 through 12.
14. Increase the SIL of the SIFs used more than once, if appropriate.
15. Ensure the risk reduction provided by the IPLs will be maintained and validated.
16. Complete and approve the LOPA documentation.

A quantitative LOPA methodology is performed based on the multiple initiating event scenarios. The benefit of quantitative LOPA is it determines a more precise numerical estimate of a SIF's required performance and a required risk reduction factor (RRF) and SIL for SIFs protecting against multiple events. The steps are:

1. Verify the effectiveness of each IPL for each initiating event.
2. Estimate initiating event frequencies and IPL failure probabilities.
3. Determine the SIL target for high-demand safety instrumented functions.
4. Determine the SIL target for continuous demand SIFs.

LOPA worksheets

Consider an example from some LOPA 2012 problem studies. A hazard and operability study (HAZOP) reviewed an amine stripping column. An excerpt of the documentation is shown in figure 1. Quantification of risk categories and frequency is shown in figure 2.

Consider the resulting developed worksheet shown in figure 3 and note this additional information about the completed LOPA worksheet:

- The column is out of service three months of every year. Because this tower is in service more than 10 percent of the time, this means no use factor may be used. If a quantitative LOPA was performed, a use factor of 25 percent could be used.
- Operation and maintenance personnel are in the vicinity of the amine stripping column approximately 15 percent of each day. Because personnel are present more than 10 percent of the time, this means no occupational factor may be used. If a quantitative LOPA was performed, an occupational factor of 15 percent could be used.
- The pressure safety valve (PSV) setting is 220 psig, and it releases to atmosphere. This means there should be another reviewed LOPA scenario with the initiating event of the PSV lifting and the consequence of potential personnel exposure to H_2S.
- The column maximum allowable working pressure is 300 psig. This means the PSV lift setting is adequate to protect the column from overpressure.
- The PSV is bench tested yearly, and this testing is documented. This means the PSV meets the auditability requirement for an IPL.
- The column pressure will increase from its normal operating pressure of 30 psig to 220 psig in approximately 15 minutes. This means no safeguards involving operator field actions can be IPLs.
- The column design feed rate is approximately 1,450 liters per minute (LPM), but recent debottlenecking has increased the feed rate to approximately 2,175 LPM. The review team is not aware of the PSV being resized for this increased feed rate. This means the PSV cannot be an IPL, because the review team does not know if the PSV is adequate for the increased feed rate. This should be noted as an action to confirm whether or not the sizing is correct for the new case.
- The spare reflux pump and low-pressure autostart are not periodically tested. Because the spare pump and autostart are not periodically tested, this safeguard fails the auditability requirement for IPLs and cannot be considered an IPL.
- The low-pressure autostart is performed in a local controller in the field that is separate from the basic process control system (BPCS). This means the spare pump and autostart could meet the independent IPL requirement based on periodical testing, even if the pressure or temperature controller was used as an IPL, since its logic is not performed in the BPCS.
- The main reflux pump is turbine driven, and the spare reflux pump is electrically driven. This means the pump power supply is independent. If the spare pump and autostart safeguard met all the other IPL criteria, it would be an IPL.
- The operators keep the column temperature control in manual approximately 25 percent of the time due to "controllability issues." This means the temperature controller cannot be used as an IPL, because it is not at least 90 percent dependable. If a quantitative LOPA was performed, a probability of failure on demand of 0.33 = (1 – 0.9 × 0.75) may be used if the temperature controller met the remaining IPL criteria.
- The column high-pressure alarm, high-temperature alarm, temperature control, and pressure control are performed in the unit's BPCS. The BPCS contains redundant control processors and is powered using a redundant power supply. Because all these functions reside in the same BPCS and the BPCS has not been designed to meet IEC 61508 or documented to meet the "proven in use" criteria of IEC 61511, only one IPL involving the BPCS may be allowed.
- The operators have a detailed procedure to respond to the reflux pump tripping, which requires the field operator to restart the pump. If the pump cannot be restarted, the control room operator must trip the steam to the reboiler. If the operating procedure was rewritten to have the control room operator immediately trip the reboiler steam after the reflux pump trips, and the review team believes each control operator would perform this action

- **Item – 1:1** • **Parameter – Pressure** • **Deviation – High** • **Cause – The reflux pump trips.**

CONSEQUENCE	SAFEGUARDS	S	L	R	CAT	RECOMMENDATIONS
The column temperature and pressure increase are causing a potential loss of containment and potential fatality due to operator exposure to H_2S.	Reflux pump low-pressure alarm. Spare reflux pump with low-pressure autostart. Column temperature control and high-temperature alarm. Column pressure control and high-pressure alarm. Pressure relief valve. Local H_2S monitors.	5	1	3	Safety	Analyze in LOPA review
S=Severity; L=Likelihood; R=Risk matrix ranking						

Figure 1. Results of amine stripping column HAZOP review

RANKS	CATEGORIES	1 First aid injury	2 Recordable injury	3 Lost time injury	4 Permanent injury or death	5 Multiple deaths
1	1 per 10 years	1	2	3	4	4
2	1 per 100 years	Tolerable	1	2	3	4
3	1 per 1,000 years	Tolerable	Tolerable	1	2	3
4	1 per 10,000 years	Tolerable	Tolerable	Tolerable	1	2
5	1 per 100,000 years	Tolerable	Tolerable	Tolerable	Tolerable	1

Figure 2. Quantifying risk categories and frequency

without hesitation, this could qualify as an IPL.

- The company LOPA procedure requires the operator be given at least 30 minutes to respond to an alarm for the alarm and operator intervention to be considered a safeguard. Assuming the company requires the field operator to have at least 30 minutes to intervene for an operator intervention safeguard to qualify as an IPL, this safeguard is not an IPL.

Final thoughts

LOPA is a valuable tool to analyze the risk associated with an event scenario and document the expected effectiveness of protective layers. When using a tool that performs analysis on single cause/consequence pairs, it is necessary to perform an additional step to determine the combined demand frequency and RRF requirement for the SIF. Failure to do so will result in an underestimation of both the initiating event frequency and the RRF target.

When a LOPA is used to determine the design basis for a SIF, it is critical that the cumulative effects of multiple initiating events be considered together when assessing IPL effectiveness and determining the SIF demand frequency and the SIL target. IPLs should be applied only against the initiating events where they are effective, thus reducing the residual risk for that scenario. Some IPLs, such as operator response to an alarm, may be considered to reduce the demand rate on a SIF when well managed and monitored by a process such as the ISA-18.2 lifecycle. IPLs should only be considered to reduce SIF demand frequency when they are well managed and monitored to ensure effectiveness. ■

SCENARIO DESCRIPTION	The amine stripping column reflux pump trips, causing the column temperature and pressure to increase, which could lead to a loss of containment and a potential fatality due to exposure to H_2S.		
DATE	01-15-12	**DESCRIPTION**	
INITIATING EVENT	Pump trip	**LIKELIHOOD**	1
CONSEQUENCE	Potential fatality	**SEVERITY**	4
UNMITIGATED RISK—TARGET SIL			4
ENABLING CONDITION(S)			**RRF**
	None		
	None		
CONDITIONAL MODIFIER(S)			**RRF**
	None		
	None		
IPL(S)			**RRF**
PIC-101	Column pressure controller		10
	None		
	None		
	None		
INTERMEDIATE EVENT FREQUENCY			2
RESIDUAL RISK—TARGET SIL			3
RECOMMENDATIONS	1. Consider making the spare pump and autostart a safeguard by periodically function testing the pump and autostart. This testing will need to be documented. This will provide an RRF of 10. 2. Consider evaluating the capacity of the PSV to ensure it can provide overpressure protection for this scenario at the new elevated feed rate of 2,175 LPM. If this PSV is found to be adequate, it will provide an RRF of 100. 3. Consider adding a LOPA scenario that will analyze the impact of the PSV lifting to the atmosphere.		

Figure 3. The resulting developed worksheet

ABOUT THE AUTHOR

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2022 Award Recognition Recipients

ISA's 2022 Honors & Awards Committee is "Celebrating Excellence" by recognizing the following individuals and groups this year.

Excellence in Technical Innovation

Uday Sheorey from Nagpur, Maharashtra, India, is recognized for the design and development of a high-resolution micro tool for retinal surgery procedures. This award, endowed by Honeywell UOP, recognizes an individual who has played a critical role in the conception, design, and/or implementation of an innovative product, process, and/or service.

Excellence in Corporate Technical Innovation

Recognizing a company whose contributions and innovations have enhanced social value, the award goes to BBA Canada in Mont-Saint-Hilaire, Quebec, for the development of a new technology that automatically converts an existing camera feed into a sensor using computer vision and artificial intelligence.

Excellence in Technical Presentation

This award recognizes the author(s) of the most outstanding paper, article, presentation, or document published and/or presented on behalf of ISA that introduces a new technology or explains an existing automation process. Brad Carlberg of Hoodsport, Wash., U.S., wins for an outstanding *InTech* article titled "Digital Twins Enable the Autonomous Paper Mill."

Excellence in Education

This award goes to an individual who has developed and/or enhanced established educational programs to advance the automation profession in educational institutions. Cesar de Prada Moraga of Universidad De Valladolid in Valladolid, Spain, wins for the development of CAD software, for teaching purposes, that has been used in various universities in Spain.

Mentoring Excellence

Richard Tunstall of Lee College in Baytown, Texas, U.S., is recognized for his excellence in mentoring students and young professionals.

Excellence in Enduring Service

This award, which can go to up to five honorees, recognizes dedicated volunteer service to the Society at the grassroots level. Mary Cannon of Houston, Texas, U.S., is recognized for years of dedicated service and leadership to the ISA Houston Section. Philip Evans of Calgary, Alberta, Canada, is recognized for years of dedicated service and leadership to the ISA Calgary Section.

Excellence in Society Service

Jose Salinas of Mexico City, Mexico, was honored for his distinguished and dedicated volunteer service to the Society.

Division Excellence

Members of the Water and Wastewater Industries Division were recognized for the development and/or execution of programs and/or services to advance the mission of the Society.

Division Leader Excellence

Simon Lucchini of Calgary, Alberta, Canada, was recognized for his outstanding efforts and contributions as a division director for the Safety and Security Industries Division.

Section Excellence

The Spain Section has been recognized for the development and/or execution of programs and/or services to advance the mission of the Society.

Section Leader Excellence

Hanumant Pansare, Pune Section President based in Pune, Maharashtra, India, is recognized for outstanding efforts to increase the membership for the Pune section and for winning the 2021 President's Membership Challenge.

Standards Excellence

This award recognizes an ISA standards committee member for exceptional efforts in organization, development, and/or administration to further the development of ISA standards and for services to advance the mission of the Society. Angela Summers in Houston, Texas, U.S., is honored for dedication in the development of ISA standards and technical reports related to safety instrumented systems.

Volunteer Leader of the Year

This award recognizes the volunteer who, in the previous year, provided the most outstanding service to advance the mission of the Society, unmatched by other leaders. This year's honoree is Bradley Churchman of Katy, Texas, U.S., recognized for outstanding service and leadership to the Houston section. ■

Groundbreaking ISA18 Committee Looks to the Future While Honoring the Memory of a Lost Leader

With the first edition in 2009, ANSI/ISA-18.2, *Management of Alarm Systems for the Process Industries*, changed the world with the introduction of activities grouped into the alarm management lifecycle. The standard has found wide use in improving the development, design, installation, and management of alarm systems across the process industries and other sectors.

ISA18 has since updated the standard (in 2016), shepherded its adoption as an International Electrotechnical Commission (IEC) standard, and is now beginning work on a third revision. At the same time, the committee has worked to develop a comprehensive series of ISA technical reports to help users better understand and implement the standard.

A major contributor to this work over many years was Bridget Fitzpatrick, who was highly regarded for her knowledge, wit, and assistance. Thus, the members of ISA18, and indeed all who worked with and knew her, were stunned and saddened by her tragic death earlier this year while on a business trip for her employer, Wood of Houston, Texas.

ISA18 has been diligent in spreading the leadership of its various technical reports, helping prepare committee members for increasingly responsible leader roles. Fitzpatrick herself served as a working group chair and lead editor, and in recent years had accepted an invitation to join the governing body for ISA standards, the ISA Standards & Practices Board. In that role, she served as the managing director of ISA18, representing the interests of the committee on the Board while also representing the Board in monitoring the activities of the committee.

ISA18 has now drawn on that reservoir of experience to help fill the leadership void from the loss of Fitzpatrick with new appointments and changing responsibilities to ensure its continuing success as the world's primary alarm management consensus standards body. Among the changes:

- Long-time ISA18 co-chair Nicholas Sands of DuPont will now become co-managing director, to be joined by Graham Nasby of CN.
- Long-time co-chair Donald Dunn of WS Nelson will be joined in that role by Kevin Brown of mCloud Technologies.
- Cristobal Ruiz of NextDecade LLC will continue to lead working group 1, a role he shared with Fitzpatrick before her passing, in a revision of ISA-18.1, *Annunciator Sequences and Specifications*. Donald Dunn will co-chair this working group.

New projects and technical reports

The first virtual meeting of a new ISA18 working group, Digitalization of Alarm Management, was held in early October. The purpose was to create a technical report on the digital transfer of data between the systems and groups performing alarm management lifecycle activities to improve efficiency, data integrity, and compatibility with other project and operation activities. The scope is defined primarily by the alarm management lifecycle activities described in the ISA-18.2 standard. The working group is led by Idar Pe Ingebrigtsen of Equinor ASA, Norway.

A technical report being developed by another working group, led by Dale Reed of Rockwell Automation and Lieven Dubois of AlarmManagement4U, is focused on alerts, events, prompts, and other notifications. The intent is to help users manage the notifications between the control system and operator that are not alarms, and other notifications not intended for the operator. The technical report is expected to be completed in mid-2023.

Work is also underway on an update of ISA-TR18.2.3, *Basic Alarm Design*, led by Todd Stauffer of Virtual Facility and Bonnie Ramey of DuPont. This document provides guidance on the types and attributes of basic alarms.

A recently updated technical report, ISA-TR18.2.5-2022, *Alarm System Monitoring, Assessment, and Auditing*, provides guidance, rationale, and examples of alarm monitoring, assessment, and audit, which are essential to achieving and maintaining the performance objectives of an alarm system. These activities can identify improvement opportunities in the other lifecycle stages, such as philosophy, rationalization, detailed design, implementation, operation, maintenance, and management of change. The update effort was led by Donald Dunn and Bill Hollifield of Hexagon.

In 2023, ISA18 will begin work on the next version of ISA-18.2. This effort and those of the ISA18 working groups are open to all ISA members and the public. If you have an interest in alarm management, please contact crobinson@isa.org or visit www.isa.org/ISA18.

Recognition

At the ISA Standards & Practices Board meeting on 9 November, three Standards Department Awards were announced that honor these ISA18 leaders:

- **Nicholas Sands**: in appreciation of his 19 years of excellence as ISA18 co-chair
- **Donald Dunn** and **Bill Hollifield**: in recognition of their leadership and expertise as working group co-chairs in the update of ISA-TR18.2.5-2022, *Alarm System Monitoring, Assessment, and Auditing*. ■

New CAPs and CCSTs

The following individuals have recently passed either ISA's Certified Automation Professional (CAP) exam, or one of the three levels of the Certified Control Systems Technician (CCST) exam. For more information about either program, visit www.isa.org/training-and-certification/isa-certification.

CERTIFIED CONTROL SYSTEM TECHNICIANS

Level 1

Craig Baurichter, U.S.
Mark Black, NEORSD, U.S.
Chester Ray Bossley, Jr., Motiva Enterprises U.S.
Richard Brown, Portland Water District, U.S.
Aaron Wayne Carlin, Motiva Enterprises, U.S.
Robert Carpenter, Florida Key Aqueduct Authority, U.S.
Arin Van Culin, Xcel Energy-Monticello Nuclear Generator Plant, U.S.
Daniel Alan Fetterolf, Motiva Enterprises, U.S.
James Adam Fetterolf, Motiva Enterprises, U.S.
Matt Ryan Holmes, Metropolitan Sewer District, U.S.
Randy Howell, St. Johns County BOCC, U.S.
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Robert Clinton Johnson, Motiva Enterprises, U.S.
Jacob Klima, Motiva Enterprises, U.S.
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Richard Marzec, U.S.
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Michael Peterson, U.S.
Joseph Pettijohn, U.S.
Robert Richards, Northeast Ohio Regional Sewer District U.S.
Adam Ridley, Motiva Enterprises, U.S.
Robert Scherpenberg, U.S.
Ryan Shane Romero, Motiva Enterprises, U.S.
Stephen Douglas Shelton, Motiva Enterprises, U.S.
Jason Stahlecker, City of Westminster, U.S.
Aaron Sturm, City of Westminster, U.S.
Timothy A. Vandrasik, NEORSD, U.S.
Robert P. Vojnovich, U.S.
Dale Lee Voyles, Motiva Enterprises, U.S.
Jon Waganer, City of Westminster, U.S.
Jonathan Williams, U.S.

CCST Specialist – Level 2

Eric Aviles Boria, City of Austin Water Utility, U.S.
Kevin G. Karagory, U.S.
Brian Keel, City of Ann Arbor WWTP, U.S.
Carlos LaLuz, U.S.
Ryan Percy, U.S.

CCST Master – Level 3

Robert L. Hopkins, U.S.
Manuel Luis Lombardero, AES Corporation, Panama

CERTIFIED AUTOMATION PROFESSIONALS

Junya Fujita, Hitachi Ltd., U.S.
Sandeep Singh, National Fertilizers Limited, India
Caitlin Sharkey, Thermo Systems, U.S.
Preston Smith, U.S

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Industry 4.0: Focus on Results, Not Industry Spin and Buzzwords

By Bill Lydon

Lydon (blydon@isa.org) is an *InTech* contributing editor with more than 25 years of industry experience. He regularly provides news reports, observations, and insights here and on Automation.com.

Automation professionals add value by focusing on what's important for their employers and guiding them, rather than mindlessly following the latest digital manufacturing buzzwords that suppliers, with their own agendas, put out to sell products. Buzzwords are a form of spin, which in the context of public relations and marketing is the selective use of nuance and facts in communication to change how people perceive the message.

It has become fashionable for marketing and public relations people to spin industry buzzwords to influence the purchase of a supplier's products. A notable example is the term Industry 4.0 and its variations, including Industry 5.0 and Industry X.0. Suppliers, consultants, and industry organizations are offering various definitions of this increasingly common buzzword, creating confusion. So, it might help to go back to the source.

My friend, Detlef Zuehlke, who many consider the father of Industry 4.0, is an industry consultant, retired professor of industrial automation, and the founder of SmartFactory-KL (https://smartfactory.de). He recently commented:

"I must point out clearly that Industry 4.0 was more randomly invented during a German press interview in 2011. So, this buzzword was never exactly defined, or even more, copyright protected. Therefore, anyone can use it in their own sense. Nevertheless, Industry 4.0 was created as a more impressive word for the upcoming fourth industrial revolution. If we follow this path, we have to understand the general meaning of an industrial revolution.

"The first revolution was the era of mechanization, and it took about 100 years before we [could name] the second industrial revolution. This occurred over about 60 years and was characterized by deep changes in electrical energy and communication technologies. Industrial revolution number three was fueled by advances in electronics and then computer technology, and it lasted for about 40 years. So, industrial revolutions are changing our lives over decades.

"Furthermore, [these revolutions] are not just covering technologies but also advances in new businesses and applications. Following this track, we may expect perhaps 30 years for the fourth industrial revolution characterized by the IoT [Internet of Things]. Therefore, I don't like using the term Industry 5.0, because it suggests the next industrial revolution is at the front door already.

"Coming back to my introductory comment on the buzzword, I guess we have to change the viewpoint. As Industry 4.0 was already a marketing phrase, so too is Industry 5.0. And I am pretty sure we will see Industry 6+.0 popping up. As the pioneer of what was called Industry 4.0, I can live with this marketing-driven view. As a scientist, not! I don't like Industry X.x at all. We should not guide our publications by buzzwords, but by remarkable scientific content."

I certainly agree with my friend Zuehlke, and I have learned much from him over the years. There are valuable and useful nonvendor architectural models and standards, including the RAMI 4.0, Reference Architecture Model Industrie 4.0 (Industry 4.0), developed by the German Electrical and Electronic Manufacturers' Association (ZVEI) to support Industry 4.0 initiatives.

It is understandable that suppliers are enthusiastic about their new products, but marketing people are not technical engineering people. Clearly, industry is shifting toward industrial digitalization and other concepts embodied in Industry 4.0, and automation professionals are serving their organizations as important change agents. Before investing in new software, hardware, and systems, they need to determine—specifically for their organizations—important factors, including goals, core ideas, concepts, and the logic of the manufacturing shift, to be competitive and profitable. Then, regardless of buzzwords and spin, engineers must perform engineering analysis to determine the best products and systems to achieve the goals.

Industrial revolutions are changing our lives over decades, and they are not just covering technologies but also advances in new businesses and applications.

Automation professionals must focus on how to improve factors like process performance, reject rates, inefficiencies, downtime, and bottlenecks for better performance, efficiency, profitability, and industry competitiveness. By focusing on these results, technical professionals can sidestep the spin. ■


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