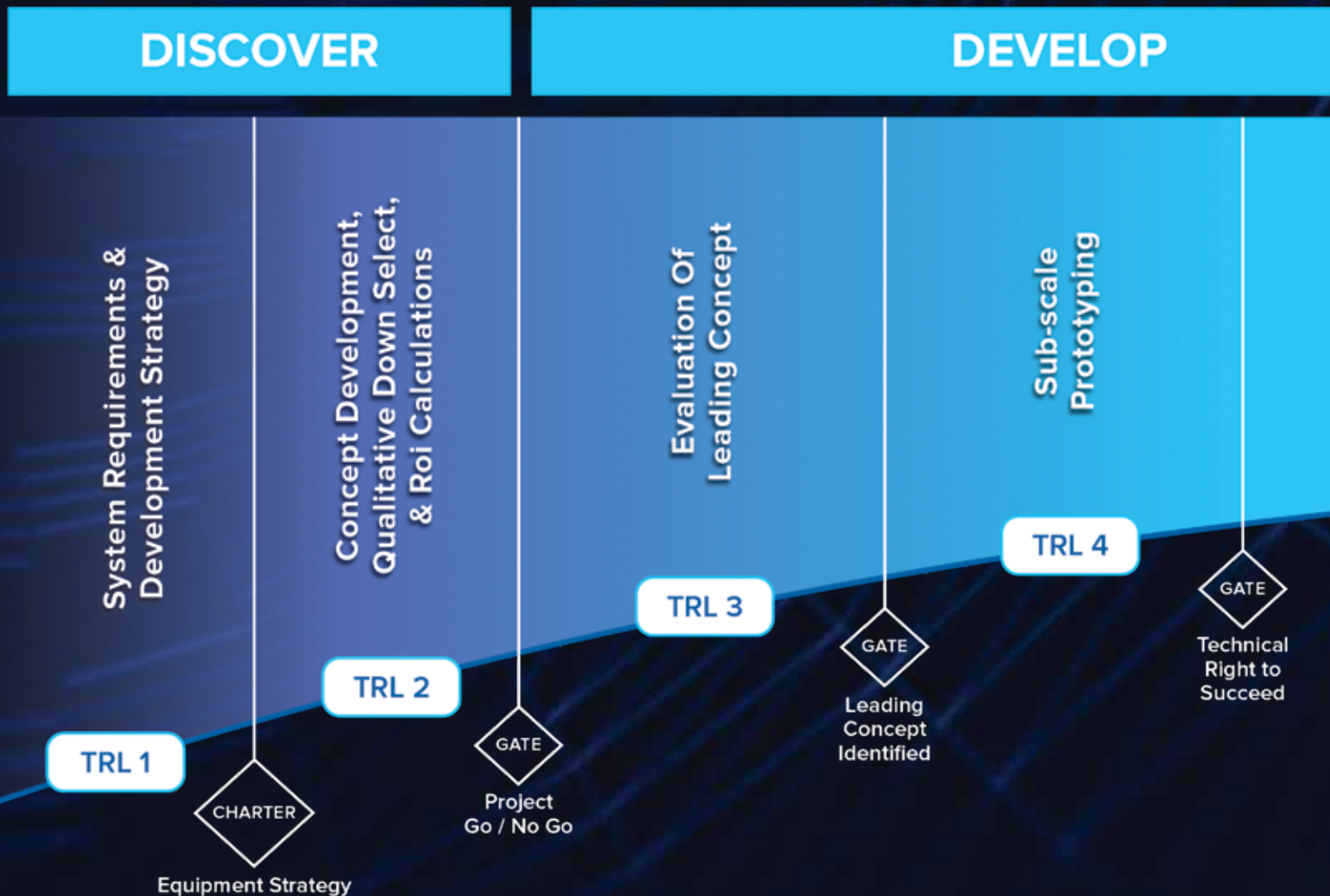


Specialized Automation and Process Equipment Development

Services offered by Stress Engineering Services

The development of manufacturing equipment and automation is a challenging task.

Most manufacturers don't require new systems all that often, but when they do, it has to be right. Stress Engineering Services, Inc. (SES) has created an equipment development process that addresses this need.



TRL 1: System Requirements & Development Strategy

Definition and documentation of requirements based on client needs. Strategic approaches to project completion developed, reviewed, and agreed upon with client.

TRL 2: Concept Development, Qualitative Down Select, ROI Calculations

Invention begins. Basic principles are observed and practical applications are invented. Applications are speculative, and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.

TRL 3: Evaluation of Leading Concept

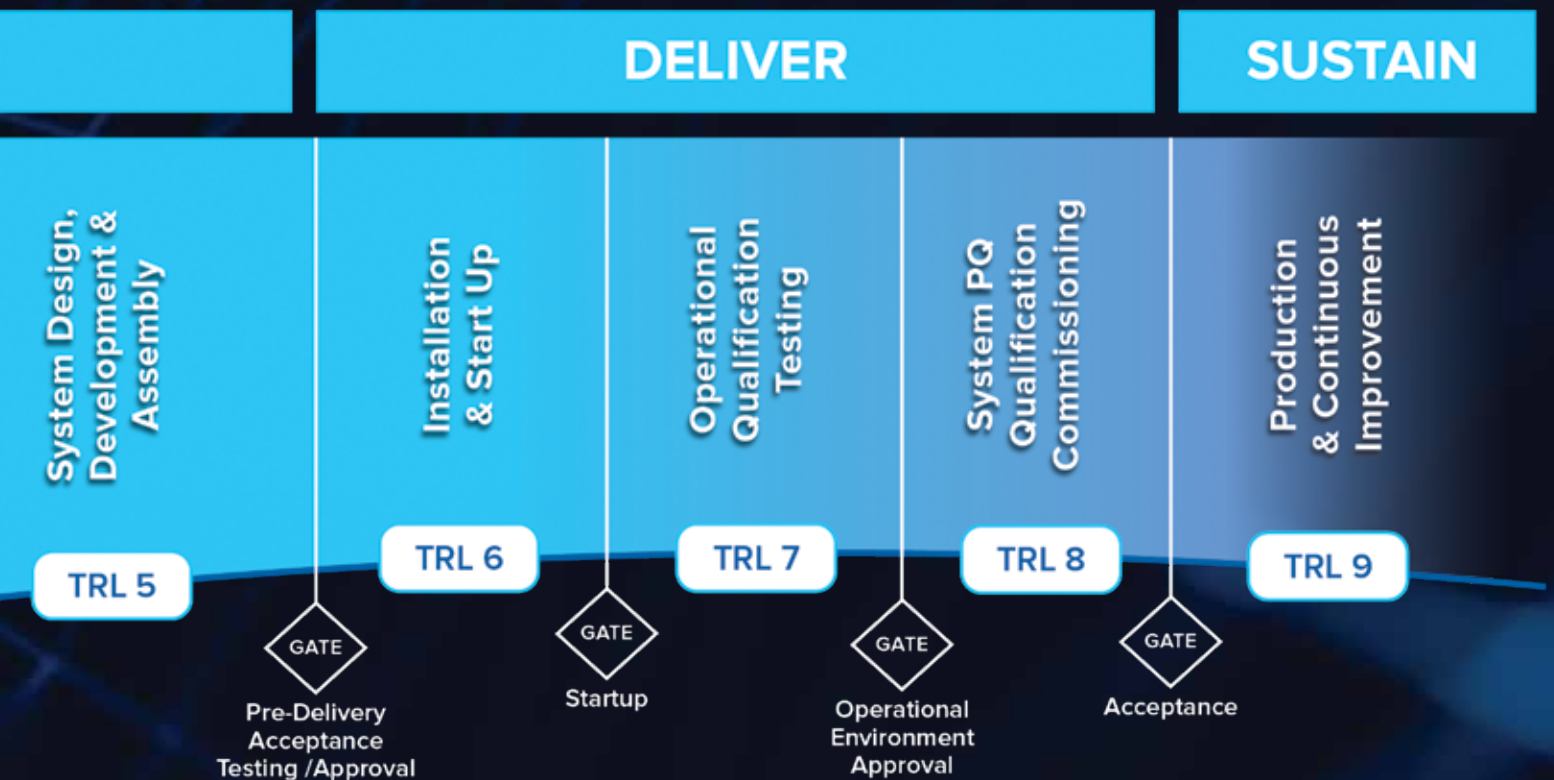
Active R&D is initiated. This includes analytical studies and laboratory studies to physically validate the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.

TRL 4: Sub-Scale Prototyping

Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared with the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.

Having the “big idea,” a machine design concept that is going to deliver quality, reliability and ROI required, is only half the challenge! A development PROCESS that is capable of delivering that equipment system is the other half.

A key component of our development process was borrowed from NASA’s “Technology Readiness Level” (TRL) assessment methodology. Disciplined application of the TRL approach ensures a clear, sober assessment of the design readiness as a requirement for advancement through a design gate. This process enforces an assessment, reassessment, and management of risks throughout the development.



TRL 5: System Design, Development & Assembly

Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so they can be testing in a simulated environment. Examples include “high-fidelity” laboratory integration of components.

TRL 6: Installation & Start Up

Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology’s demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in a simulated operational environment.

TRL 7: Operational Qualification Testing

Prototype near or at planned operational system. Represents a major step up from TRL 6 by requiring demonstration of an actual system prototype in an operational environment.

TRL 8: System PQ Qualification Commissioning

Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Testing is conducted to determine if design requirements have been met.

TRL 9: Production & Continuous Improvement

Actual application of the technology in its final form and under real world conditions.

1. Technologies to Enable Autonomous Detection for BioWatch: Ensuring Timely and Accurate Information for Public Health Officials : Workshop Summary. E - Technology Readiness Levels in the Department of Defense. Board on Health Sciences Policy; Board on Life Sciences; Institute of Medicine; National Research Council; Hook-Barnard I, M. Posey Norris S, Alper J, editors. Washington (DC): National Academies Press (US); 2013 Dec 31.


2. Technology Readiness Assessment (TRA) Guidance. U.S. Department of Defense, April 2011.

SYSTEM REQUIREMENTS AND DEVELOPMENT STRATEGY

Based on Client Needs

For equipment development projects, the die is cast very early. If the requirements are ill-defined, project success is in jeopardy! **For that reason, we work very hard with our clients to define very clearly, with as much quantitative information and data as possible, what success looks like.** We recognize that it is impossible to nail everything down, but it's critical to nail

down as much as possible and put placeholders for the "unknown unknowns" wherever appropriate. A well thought out requirements document still does not eliminate the curveballs that inevitably will happen. **However, our process is flexible enough to accommodate the adjustments needed to be successful.**



Machine Requirements Document

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CALGARY (513) 336-6770

SYSTEM LEVEL REQUIREMENT ID #	SOURCE: TOP LEVEL NEED ID #	PARENT REQUIREMENT STATEMENT	SYSTEM LEVEL REQUIREMENT STATEMENT	PRIORITY
SYS-XXX	01	Automate the process to produce roll-your-own PRODUCT X	The PRODUCT X machine process forces shall not exceed the strength of the raw materials.	REQUIRED
SYS-XXX	01	Automate the process to produce roll-your-own PRODUCT X	The automated PRODUCT X machine can be operated at full speed with a work crew of X or fewer people.	REQUIRED
SYS-XXX	06	Automate the process to produce roll-your-own PRODUCT X	The automated PRODUCT X machine will accommodate a product with a wrapped mandrel.	DESIRE
SYS-XXX	06	Automate the process to produce roll-your-own PRODUCT X	The automated PRODUCT X machine will accommodate a product with a wrapped mandrel.	DESIRE
SYS-XXX	02	Retain features which support the current product patent	Total area for the PRODUCT X machine associated support shall be less than X ft2.	MANDATORY
SYS-XXX	03	Install PRODUCT X machine at COMPANY X facility in Connecticut	Shipping and receiving activities shall not interfere with existing COMPANY X activities.	REQUIRED
SYS-XXX	03	Install PRODUCT X machine at COMPANY X facility in Connecticut	All Connecticut labor laws shall be followed.	DESIRE
SYS-XXX	07	Install PRODUCT X machine at COMPANY X facility in Connecticut	Flavor shall be applied as a liquid.	MANDATORY
SYS-XXX	07	Install PRODUCT X machine at COMPANY X facility in Connecticut	The packaged product shall have a minimum shelf life of two years.	MANDATORY
SYS-XXX	04	Install PRODUCT X machine at COMPANY X facility in Connecticut	The final product shall have a minimum shelf life of two years.	DESIRE
SYS-XXX	05	Maintain current product quality	The final product shall have no cracks or cuts longer than XX in any location more than YY from the sheet edge when removed from the pouch.	REQUIRED
SYS-XXX	05	Maintain current product quality	The production systems shall maintain a minimum moisture level of XX% for all materials.	REQUIRED
SYS-XXX	05	Maintain current product quality	The equipment shall be corrosion-resistant for 10 years when used in an operating environment as described in the Update Model.	MANDATORY
SYS-XXX	06	Generate \$3.5 - \$4 MM savings in operating costs per year	The PRODUCT X machine shall operate at a process total burdened cost shall be less than X per Y units.	DESIRE
SYS-XXX	06	Generate \$3.5 - \$4 MM savings in operating costs per year	Good Manufacturing Practices (GMP) shall be implemented.	REQUIRED
SYS-XXX	06	Generate \$3.5 - \$4 MM savings in operating costs per year	The equipment shall meet OSHA regulations XYZ.	REQUIRED
SYS-XXX	06	Generate \$3.5 - \$4 MM savings in operating costs per year	Total PRODUCT X machine development costs shall not exceed \$X million.	MANDATORY
SYS-XXX	06	Generate \$3.5 - \$4 MM savings in operating costs per year	Total PRODUCT X machine capital costs shall not exceed \$X million.	DESIRE
SYS-XXX	07	Comply with expected regulatory standards, regulations, and guidance	The equipment shall meet OSHA regulations XYZ.	REQUIRED
SYS-XXX	07	Comply with expected regulatory standards, regulations, and guidance	Total PRODUCT X machine development costs shall not exceed \$X million.	REQUIRED
SYS-XXX	07	Comply with expected regulatory standards, regulations, and guidance	Total PRODUCT X machine capital costs shall not exceed \$X million.	REQUIRED
SYS-XXX	08	Provide a 2-year return on investment		

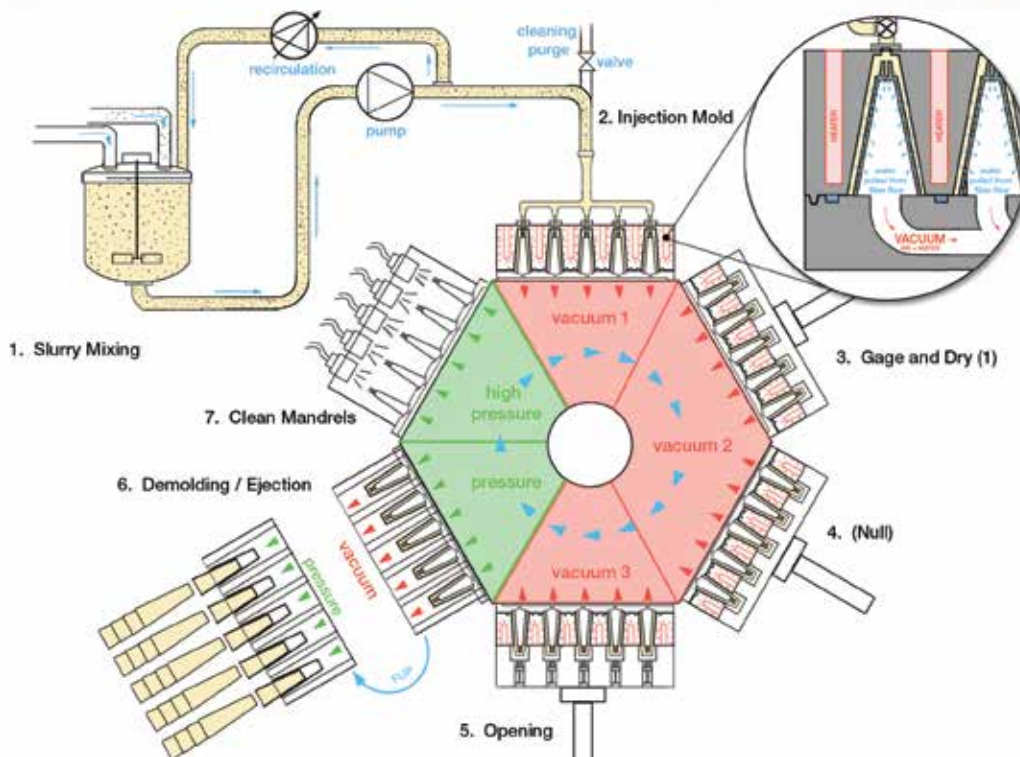
CONCEPT DEVELOPMENT, QUALITATIVE DOWN SELECT, ROI CALCULATIONS

Getting Started with Big Ideas

A really successful machine development project begins with the “big idea” that can be exploited to deliver performance for the right price. **SES’s approach to concept development brings together the talents**

of creative industrial designers, subject matter experts, engineers, and machine designers. Our process rapidly distills diverse ideas into the leading concepts for consideration.

A leading candidate is identified by completing a qualitative assessment of all the design concepts based on complexity, schedule, cost, and the manufacturing environment into which it will be placed.



We bring together industrial designers, subject matter experts, engineers, and machine designers to develop divergent ideas that are then rapidly distilled into leading concepts for consideration.



TRL

3

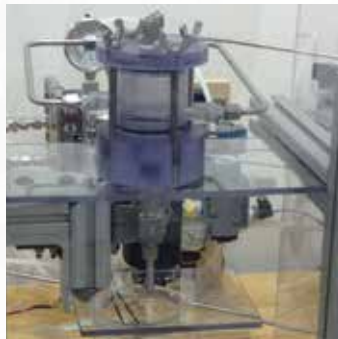
EVALUATION OF LEADING CONCEPT

The Art of Killing Bad Ideas Fast

This is when active R&D is initiated. This includes analytical studies and laboratory studies to physically validate the analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.

Regardless of whether the development is focused on mechanical automation or the development of a fluid/thermal process system, SES uses a very rigorous, physics- and testing-based approach of performance analysis, simulation, and bench scale testing to vet leading concepts before a commitment is made to

any particular development pathway. **In the long run, this approach kills the bad ideas quickly, before significant investment of resources and time are made. This approach reduces project risk.**



SES relies heavily on early exploratory experimentation, "Frankenstein" prototypes, and predictive computational analysis to evaluate design concepts quickly.



TRL

4

SUB-SCALE PROTOTYPING

Early prototyping, supplemented by simplified analytical and computational modeling, is at the heart of our development process. Basic technological components are integrated to establish that they will work together. This is relatively “low fidelity” compared with the eventual system. Examples include integration of “ad hoc” hardware in the laboratory.



Functional “works-like” prototypes are developed to demonstrate the merits of an idea as early as possible.

To stay at the cutting edge of prototyping technology, in addition to our in-house machining and 3D printing capability, we also rely on partner machine shops and service bureaus to quickly execute prototyping to advance and demonstrate functionality.



This image highlights an Alpha prototype of an electro-mechanical machine element developed by SES.

TRL

5

SYSTEM DESIGN, DEVELOPMENT & ASSEMBLY

ALPHA & BETA EQUIPMENT BUILDS: *Mapping to Manufacturing*

Whereas early prototyping, bench-scale testing, and engineering analyses are used to identify the foundational concept upon which the equipment system development will rest, **the Alpha (process feasibility) and Beta (production capability) phases of development are where the mapping of specific unit operation design are integrated into a complete manufacturing system.**

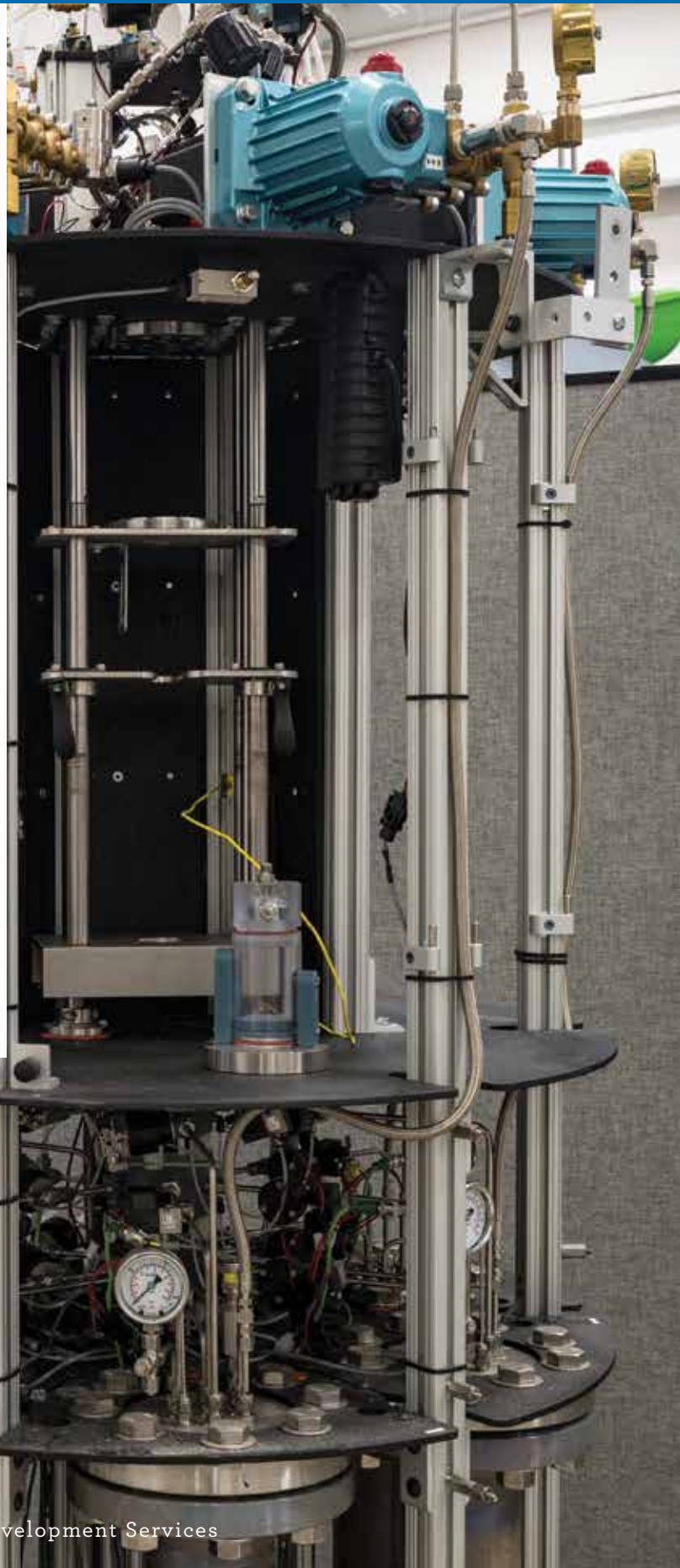
The Alpha prototyping phase is typically where the integration of the new process elements begins and where assembly challenges are addressed. The ultimate goal is to

demonstrate cohesive performance of the functional operations.

Beta prototyping is designed to demonstrate a fully functional system. It is not uncommon for the Beta hardware to be drafted into early production for lead market studies and lead market production.



Beta prototype of a custom robotic filling system.



MACHINE AND PROCESS CONTROLS: *Building to Suit Each Organization*

SES is mindful of the varying levels of technical depth operators and maintenance staff may have and takes that into consideration when the machine is being designed. Working with the client's manufacturing organization, important high level controls strategy and guidance are established. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment. Examples include "high-fidelity" laboratory integration of components.

Several key factors used to guide the development include, but are not limited to:

- Will the new equipment be tied into the MES and/or ERP system?
 - What are the machine control requirements (low cost custom boards and programming or PLCs, distributed control, SCADA architecture)?
 - Is remote monitoring (IIoT) and maintenance desirable?
 - Does the equipment need to be IIoT ready?
- Several key factors used to guide the development include, but are not limited to:
- What is the existing skill set within the current operation?



Electrical controls development for a pharmaceutical product pilot plant developed and started up at SES.



TRL

6

INSTALLATION & START UP

Production Platform

This represents a major step in a technology's demonstrated readiness. If the system is a one-off, more often than not, the Beta prototype becomes the pilot scale or production platform. If multiple machines are contemplated, SES will construct, start-up, centerline, and validate the equipment for pilot

line production. It is possible to conduct this process at our facility, provided all the required services are available. Upon acceptance by the client, the equipment will be relocated to the client's production site, started-up and re-centerlined. Training will be provided to local operations and maintenance staff.



SES has nearly 160,000 sq ft of lab space, much of which can be used for assembly and start-up of process and mechanical equipment systems.



TRL

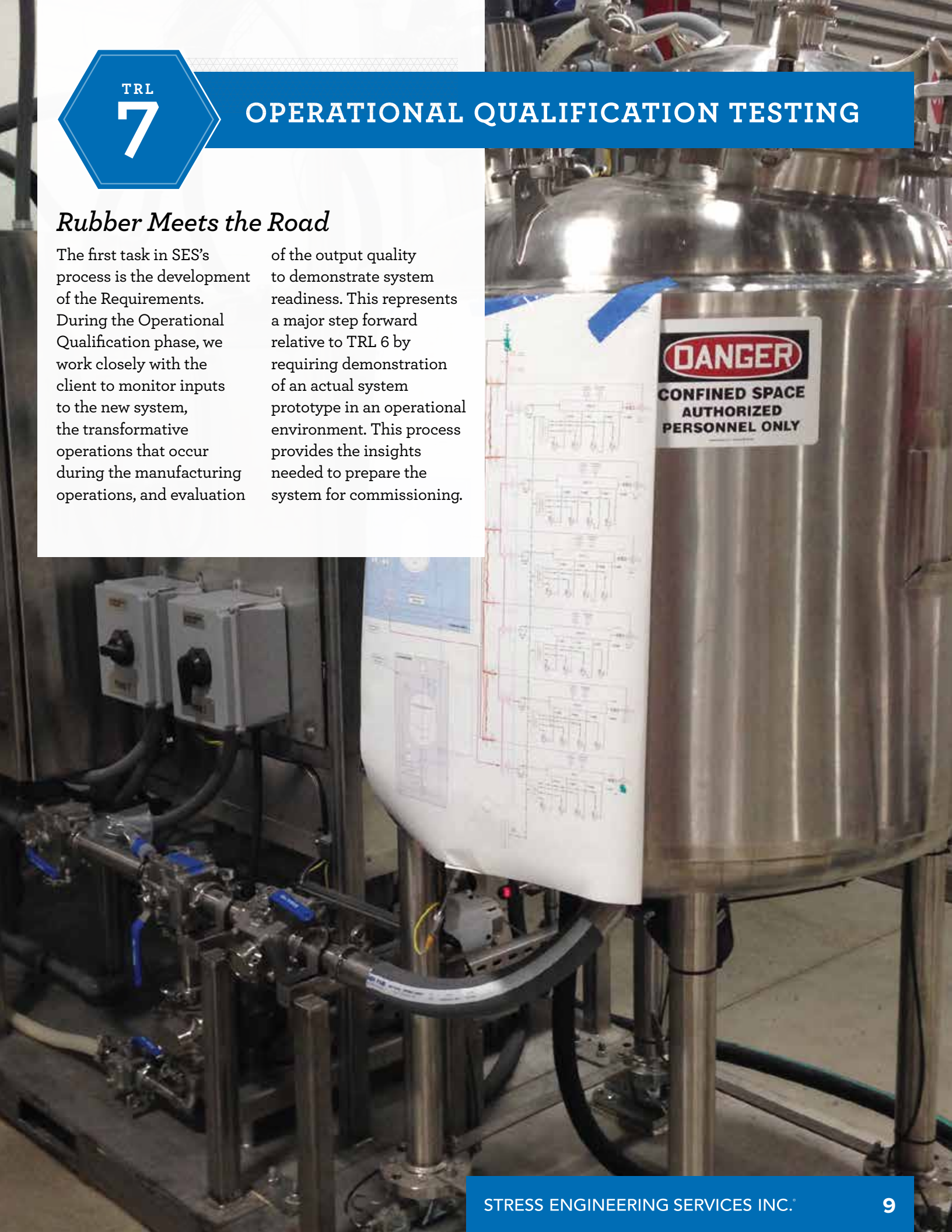
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OPERATIONAL QUALIFICATION TESTING

Rubber Meets the Road

The first task in SES's process is the development of the Requirements. During the Operational Qualification phase, we work closely with the client to monitor inputs to the new system, the transformative operations that occur during the manufacturing operations, and evaluation

of the output quality to demonstrate system readiness. This represents a major step forward relative to TRL 6 by requiring demonstration of an actual system prototype in an operational environment. This process provides the insights needed to prepare the system for commissioning.



TRL

8

SYSTEM PQ QUALIFICATION COMMISSIONING

Nearing the Finish Line

The system PQ Qualification Commissioning is the true end of the development process and confirmation that the operational performance meets the requirements. The technology has been proven to work in its final

form in the manufacturing environment. In almost all cases, this TRL represents the end of true system development. **At this point, the equipment is ready for production service!**



PRODUCTION AND CONTINUOUS IMPROVEMENT

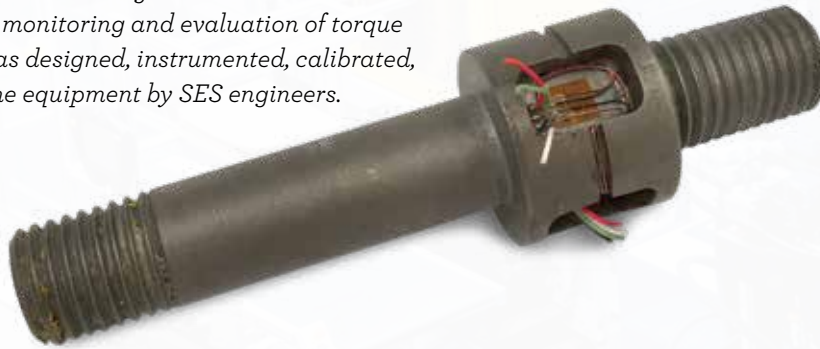
IIoT READY SYSTEMS: *Data Streams and Data Analytics*

Most of SES's manufacturing clients are interested in IIoT-ready equipment/manufacturing systems. As a machine developer, SES is uniquely positioned to integrate sensors, either custom or commercial, into manufacturing systems

in ways that most others cannot. **Our uniqueness stems from the fact that we are able to not only provide the new data stream(s) as part of the development, but can also deliver the data analytics and validated**

“digital twins” to enable the development of near real-time actionable insights, which can be leveraged to improve OEE (Overall Equipment Effectiveness).

Example of a custom element integrated into a machine that enabled the real-time monitoring and evaluation of torque variation. The bolt was designed, instrumented, calibrated, and integrated into the equipment by SES engineers.



PROJECT MANAGEMENT: *With You From Start to Finish*

Project management is critical to equipment development programs because the diversity of skill sets, technology and technical details required on even the most basic systems. Real-world insight is invaluable for successful and efficient project execution, from strategy and inter-discipline coordination to manufacturability and start-up. **Our Project Managers are the client's**

representatives and must be focused on optimizing total costs with the appropriate balance of engineering, capital/procurement, construction, and startup expenditures. No process is perfect, but experience in avoiding conflicts and minimizing delays offers the best potential for a successful project that is on time and on budget.



Seamless integration of technical and commercial disciplines.

The key elements of a successful equipment development project require seamless integration of many technical and commercial disciplines, such as design engineering, structural mechanics, fluid/thermal sciences, material science, electrical engineering, sourcing, industrial design, human factors, and economics. SES has the multi-disciplinary team needed to tackle the complex challenges

of mechanical and process manufacturing equipment development.

We can operate as consultants, integrated partners or stand-alone developers to offset the internal capacities of our clients. Ultimately, we help our clients succeed faster with ideas, expertise and teams scaled to suit the challenges unique to each company.

Leveraging 45+ years of custom equipment development.

Not long ago, machinery and equipment developers supporting the demand for new manufacturing equipment could be found in abundance throughout the country. Changing business strategy, evolution in skilled worker demographics, and economic pressure from off-shore sources have significantly reduced the availability of competent machinery and process development companies to support your manufacturing equipment needs.

Stress Engineering Services (SES) has actively pursued a strategy of investment and growth to support a range of specialized manufacturing equipment development markets.

This investment in staff and facilities, coupled with more than 45 years of custom equipment development experience, has propelled SES's specialized equipment development group to the forefront of our services portfolio. Our experience ranges from the development of relatively simple semi-automated assembly equipment to complex, fully automated machinery for both small companies and multi-national manufacturers.

Although not exclusively so, our services are highly leveraged for projects from early concept development and technical right-to-succeed through prototyping, pilot-scale build and pilot line start-up. We also leverage our signature predictive analysis capabilities to reduce development risk and schedule as appropriate in the project.

Our services are highly leveraged for projects from early concept development and technical right-to-succeed through prototyping, pilot-scale build, pilot line start-up, and production start-up.

When you need a partner to help with equipment automation projects from early concept development and technical right-to-succeed through prototyping, pilot-scale build and pilot start-up, let's have a conversation.

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