Professional Development

Lean Concepts

Opportunities for safety professionals

By Fred A. Manuele

Applying Lean Concepts to eliminate waste, improve efficiency and lower production costs has become popular among senior-level management. Minimizing waste is the base on which lean concepts are built. A lean endeavor seeks to eliminate activities or processes that consume resources, add cost or require unproductive time without creating value. The concepts can be described as striving for excellence in operations in which each employee seeks to eliminate waste and participates in the smooth flow of value to the customer.

For safety professionals, lean represents an opportunity to make substantial contributions to the business process. When a lean initiative is proposed, safety professionals should tactfully and assertively call management’s attention to an element of waste that should be addressed in the lean process—waste arising from the direct and ancillary costs of accidents. For example, a safety director whose staff had convinced management through its accomplishments that they add value to the business process asked to be a part of the concept discussions as soon as he heard that lean concepts were being considered. He says management quickly recognized that his counsel would be valuable in eliminating the waste which derives from accidents. (Another example of how SH&E staff was extensively involved in a lean design activity begins on p. 31.)

Direct accident costs are substantial—those costs are a form of waste. Ancillary costs, such as those related to interruption of work, facility and equipment repair, idle time of workers, training of replacements, and investigation and report preparation, may represent a greater amount of waste than direct costs. For incidents that result in severe injury—particularly when property damage is extensive—the ancillary cost and accompanying waste can be substantial.

Addressing Hazards & Risks Early in the Lean Process

Since the goal is to minimize waste and reduce costs, it is logical to address safety considerations early in the lean process rather than as an afterthought. Unfortunately, many attempts at achieving lean have not included—or worse, have compromised—safety considerations. As a result, human capabilities and limitations may be given less consideration than is necessary to avoid injuries. Thus, hazards and risks are increased.

The author has observed situations similar to those about which Newman and Braun (2005) offer caution with respect to poorly designed tasks that do not adequately consider human limitations. Unfortunately, lean doesn’t necessarily mean safer though the two should go hand in hand. After all, a poorly designed task that requires a worker to reach excessively is not only inefficient, requiring more time and motion than needed, but is also likely to cause injury. Similarly, a worker lifting materials beyond his or her own capabilities takes more time and energy to perform the task and runs the risk of overexertion.

In the worst-case scenario, an overzealous company may implement extreme lean manufacturing strategies where safety is not merely overlooked, but compromised. In the end, increasing efficiency without incorporating safety will cost far more than it saves.

Minimizing handling and storing of materials and work in process, and avoiding interruptions in the workflow are central in the lean process. While all hazards and risks should be addressed in a lean process, applying ergonomics principles—both human and engineering—fits particularly well as the lean process moves forward. Another factor of waste to be avoided is the retrofitting expense and production time lost to correct hazards that may arise as a drive for lean is pursued.

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Gilbreth, who was a proponent of scientific management and motion study; Walter Shewhart, a pioneer in statistical control; and W. Edwards Deming who achieved renown for his work in quality management.

Whatever the origins of the concepts, the leaders at Toyota, as they pursued operational excellence, combined, refined and converted them with great success into what is now called lean in the U.S.

Lean Concepts Are Broadly Applicable

While the early literature on lean concepts describes their application in manufacturing, the concepts have been adopted to minimize waste in a wide range of enterprises and activities—from accounting systems, depot operations, service businesses and transportation companies, to warehousing, construction, healthcare facilities (including entities as small as group physician practices), product quality improvement and environmental management. The concepts also have been used to eliminate non-value-added e-mail.

Safety professionals with environmental management responsibilities may want to download EPA's The Lean and Environment Toolkit Version 1.0 (EPA, 2006). A major section in the toolkit is titled “How to Incorporate Environmental Considerations into Value Stream Mapping.”

How broadly have lean concepts been applied? Using the phrase “lean concepts” in an Internet search returns more than 11 million results. Clearly, getting into lean concepts spells opportunity for safety professionals.

A Significant Opportunity

One colleague, John Garis, believes becoming engaged in the lean process presents SH&E professionals with a noteworthy opportunity.

I am an independent contractor specializing in safety and industrial hygiene. Two of my clients are engaged in a lean manufacturing process. I find safety to be very compatible with the lean process. In fact, I have a sense that lean can be used to elevate the overall safety aspects into that realm that we as safety professionals have talked about for decades—that is, the engagement of everyone from senior executives to department managers, to line supervisors and finally to the hourly staff into the safety process.

To do that well, an important first step is to treat safety as an ongoing process rather than a program. Lean is a continuous improvement process, not a program. My accounts that have achieved success with lean and continuous improvement for the prevention of waste and manufacturing errors are also successful in instilling those same “process” ideas into safety.

Origin of the Lean Concept

Much of the literature recognizes Taiichi Ohno as the originator of the lean concept about 50 years ago, while he was with Toyota—a company that has been highly successful in applying the concepts. However, some literature also reports that the concepts were applied in the early 1900s by Henry Ford, who created the first “lean” auto production line; Frank Bunker

Abstract: A lean endeavor seeks to eliminate activities or processes that consume resources, add cost or require unproductive time without creating value. The application of lean concepts throughout business and industry presents an opportunity for SH&E professionals to call management’s attention to an element of waste that should be addressed in the lean process—waste arising from the direct and ancillary costs of accidents.
Definitions
Given its origins, several terms associated with lean concepts are Japanese. Following are abbreviated definitions of those terms as they are applied in the design process discussed here, along with several other key definitions.

- **Flow**, as a goal in the lean process, is achieved after waste is removed from the system and the improved process (value stream) runs smoothly and efficiently with a minimum of waste in the work of personnel or in equipment downtime.

- **Jidoka** refers to machines or the production line itself being able to stop automatically when abnormal conditions arise—such as when a machine breaks down or temperature rises beyond a set limit. Jidoka applications do not allow defective parts or products to go from one workstation to another.

- **Kaizen** in Japanese means change for the better. In American English, the term has come to mean continuous improvement. For the purpose of this article, the emphasis in applying the continuous improvement process is to eliminate waste (those activities that add to costs but do not provide value).

- **Muda** encompasses all activities that wastefully consume resources but do not add value. Seven types of waste were identified at Toyota for which continuous reduction was to be obtained.

  1. **Defects** in products or services are wasteful in that they consume material and require additional production and correction time.

  2. **Overproduction** is the production or acquisition of items beyond what is actually needed. Where this occurs, additional capital investment is necessary, and costs are increased since additional storage space is necessary, but no value is added. It also results in excessive material handling and its accompanying risks.

  3. **Transportation** waste is that which requires additional and unproductive moving of a product in process. Each time a product is moved there is added risk of damage to the product, equipment and facilities, as well as of harm to personnel. In the moving process, the product fills valuable space and requires time expenditures without adding value.

  4. **Waiting** refers to both the unproductive time spent by workers waiting for material or components in a process to arrive and the time required for excess production to flow through the system. Another example is material or information waiting to be worked on to complete a customer order. Similar wastes occur when incidents that could result in injury occur.

  5. **Inventory** in excess of what is needed requires an additional capital outlay and produces waste because of the additional storage space and handling time involved. As noted, frequent handling of inventory adds to the risk of injury.

  6. **Motion** refers to workers’ unproductive time and movement where the process is cumbersome, inefficient and wasteful. This implies that the process also may be hazardous.

  7. **Overprocessing** means using a more expensive or otherwise valuable resource than is needed for the task. It also includes costly rework.

- **Poka yoke** means mistake-proofing or foolproofing. The purpose is to design work and processes so that it is nearly impossible for people to err. An example is designing hose or electrical connections so that they can be assembled in only one way, thereby reducing risk. This is an important, yet often-neglected concept with respect to employee and product safety.

- **Mura** pertains to unevenness in the workflow. The goal is steady workflow.

- **Muri** relates to avoiding overburdening equipment or employees. The goal is to reduce overburden to acceptable levels. For equipment, that might require operating at 80% of the specified limit; for employees, designing work methods that are overly stressful and working excessive hours is to be avoided.

- **Pull** defines the operational situation after which much has been accomplished in applying the lean process and inventories can be maintained in relation to the “pull” as represented by customer orders. Waste from having excessive inventory (and all that implies) is minimized (e.g., the cost of excess space, the financing of the excess inventory, the cost of additional handling of inventory).

- **Total productive maintenance** ensures that all equipment used in a process can always perform its tasks so that production or work processes will not be interrupted.

- **Value stream** includes every step in a process to produce a product or provide a service—from the receipt of materials to the delivery of the product or service.

- **Value stream mapping** is the written or computer-based identification of each step in the value stream to identify the sequence of activities and information flows to produce a product or deliver a service (see sidebar on pg. 31). This is a vital step because it provides opportunity for team brainstorming to identify activities that do not add value. Lean practitioners use value stream mapping to:

  1. Identify major sources of non-value-added time in a value stream;

  2. Envision a less-wasteful future state;

  3. Develop an implementation plan for future lean activities.

On the Lean Literature
One can find plenty to read on lean, but popular texts contain few references to accidents as a waste factor. This is demonstrated, for example, in Lean Thinking: Banish Waste and Create Wealth in Your Corporations (Womack & Jones, 2003). According to its dust jacket, the book “has been sold in the hundreds of thousands of copies in a dozen countries.” Obviously, it is a popular book, but it contains few references to accidents as a waste factor.

For safety professionals, that omission represents both a problem and an opportunity to make their presence felt. Progressive safety professionals will recognize this shortcoming—the nonrecognition of
A Simplified Initial Value Stream Map
Identifying Waste (Muda) & Opportunities for Continuous Improvement (Kaizen)

A Major Work in Progress

Other safety professionals have recognized the absence of safety in the lean literature. They also have encountered situations where safety concepts and lean applications were in conflict, leading to unsatisfactory results. Association for Manufacturing Technology (AMT) is finalizing a technical report titled Designing for Safety and Lean Manufacturing: A Guide on Integrating Safety and Lean Manufacturing Principles in the Use of Machinery, which is to be published as ANSI B11.TR7-2007 in mid-2007.

The abstract from the report is as follows (reprinted with permission).

TR7 Abstract

Lean manufacturing includes a variety of initiatives, technologies and methods used to reduce waste, costs and complexity from manufacturing processes. The intent of applying lean concepts is to achieve better and faster throughput with less waste and the related benefits thereof. However, in the effort to get lean, safeguarding systems intended to protect personnel can be defeated resulting in greatly increased risks. Yet safety can be effectively included in the lean manufacturing effort to yield processes that are better, faster, less wasteful and safer. This document provides guidance for persons interested in how to concurrently address lean manufacturing concepts and safety concerns of machinery.

A brief overview of lean manufacturing concepts is presented and examples demonstrate situations where this has not occurred. The challenge of concurrently addressing safety and lean is described and examples demonstrate situations where this has not occurred. A process model for safety and lean is presented. A risk assessment framework is outlined that demonstrates how lean manufacturing concepts and safety can be implemented concurrently.

Examples of where safety and lean have been successfully applied are shared. This document also provides design guidelines on how to meet lean objectives without compromising safety.

Although its purpose is to address lean and safety concepts in the use of machinery, the report will be valuable to all safety professionals who become involved in lean. Its content is largely generic and the principles apply to all enterprises.

As its title implies, the report will be an excellent resource for those who want to understand how the lean process and safety principles can be melded to reduce waste while maintaining acceptable risk levels. TR7 provides guidance—from the initial concept stage for design and redesign through to operational waste reduction applications—on how the lowest waste at the lowest risk can be achieved, and helps fill the gap in the technical literature on the topic.

Merging Lean & Design Concepts

All but one application of lean concepts with which the author has become familiar involve removing waste from operating systems. In the one exception, a pharmaceutical company merged lean concepts into the original design considerations for a major project in which new equipment was to be acquired and installed in an existing facility. In lean language, that would be a “brownfield” application.

When design engineers incorporate lean concepts into the design of an entirely new facility that is a “greenfield” application.
What the pharmaceutical company has done is an excellent example of how lean and safety can be addressed concurrently in the design process. Although this is unique, imaginative and creative in the author’s experience, the idea has been applied elsewhere. For example, Womack and Jones (2003) report that lean concepts were applied in the design of the Toyota auto manufacturing plants built in the U.S.

This company’s initiative also is particularly noteworthy in that it incorporates relative provisions in ANSI/AIHA Z10-2005. Those provisions are:

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<td>Risk assessments</td>
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<td>Hierarchy of controls</td>
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This article presents an abbreviated version of this company’s process. It is close to the theoretical ideal—and safety professionals can learn from it.

**Criteria for Applying the Lean Design Process**

In this company, use of the lean design process commences when an assumption is made that a project is of such magnitude that it will require following the steps outlined in the firm’s Request for Capital Expenditure Procedure. Practical application of the process has been demonstrated in the company that developed it. All operations personnel at this location have received lean training.

For purchases below the capital expenditure request level, the basics in the process are applied but not as extensively. For example, if the machine shop supervisor requests the purchase of a metal-cutting saw, safety considerations would be established and they would be reviewed by SH&E professionals as well as more than one level of management. Those safety requirements would be included on the purchase order. Once the equipment was received and installed, a safety validation would occur.

**The Company’s Lean Design Process**

1) **The Concept Stage**

An idea for process improvement may be proposed by any source—research and development, engineering, any operations department, a cross-functional group, maintenance, individual workers. A broad range of team-based brainstorming then takes place.

If it is concluded that the idea should be pursued and the expenditure level requires following the organization’s capital expenditure procedure, the team seeks senior management review and tentative approval. A project manager is assigned as well.

2) **Capital Expenditure Request**

The capital expenditure request would describe the project’s design objectives, make the business case for it and request the necessary funding. In this company, each of the 26 elements in its safety management system is assigned to a champion, who most often holds an upper-level management position. For example, the CEO assumes direction and accomplishment responsibility for two of those elements, while four are assigned to a senior manufacturing executive. At this stage, all safety management system element champions are aware of the project and each must sign off on it.

3) **Identify the Customers/Users**

A customer/user in this context means every employee who may be affected by proposed process revision. It really means everyone. The purpose is to ensure that all those who could be affected are aware of the proposed process change and can provide input as the activity proceeds.

Identifying the customers/users is considered an important step in the lean process. With respect to external customers, the characteristics of the products manufactured are agreed upon; product amounts that will be purchased and over what time spans are estimated; inventories are tightly controlled; and delivery methods and schedules are arranged.

4) **Project Customers/Users Requirement Specification**

At this point, a senior-level manager prepares a document expanding on the original idea. This document contains enough detail to specify the outcomes expected and some criteria are established. Customers/users may submit their specifications and suggestions on how waste can be eliminated.

5) **Value Stream Map**

A value stream map is created at this point. This is a preliminary flowchart that includes each step of the production process as conceived at this time—from raw material receipt to product shipment. It is an important step in that it documents the processes to be considered as the waste potential is eliminated.

6) **Project Conceptual Design**

All that preceded this step in the process influences the drafting of the project conceptual design. It shows the proposed layout, as well as building and utility impacts, and contains specifics on the major equipment needed. SH&E considerations are addressed at this stage as well.

Over time, this company has evolved design specifications that are unique to its needs. SH&E specifications are incorporated in them. (In researching how companies meet the design review provisions in Z10, the author has found that universally applied design standards do not exist. Each company’s engineering personnel draft the standards they consider appropriate.)

The following personnel review and sign off on the concept design: operation executives; subject-matter experts; SH&E professionals; engineering; maintenance personnel; and the building manager.

7) **Change Control Provisions**

This company operates under the regulations of several governmental entities. Therefore, a rigid change control system is in place to ensure that all quality, safety and environmental requirements are met. Food and Drug Administration (FDA) is one of
The 5S Concept

Simplifying is the next step. If there is a place for everything retained, and those places are well marked and labeled and are known to staff, it is easier to find tools, parts and the equipment needed to do a job and keep things orderly. Simplifying in a disciplined manner promotes identification of hazardous situations and makes it easier to get things done with less risk.

Systematic cleaning is the third step in 5S. Everyone is to be involved in this endeavor. Workers in a unit are assigned ownership of and responsibility for the cleaning tasks. The purpose is to produce orderliness. Dirt, disorder, and items blocking aisles or stored in some manner that makes their retrieval hazardous are not tolerated. The cleaning processes focus on enhancing operational efficiency, eliminating waste and reducing risk.

Standardization, the fourth step, is to adopt the best practices for equipment and machinery layout, and design of equipment and work practices for productivity, mistake-proofing and continuous improvement. Workers at all levels have opportunities for input into the standardization procedure. Comments are sought on the design of the work methods for efficiency as well as to minimize risks.

At the location in this case, accidents are recognized as a form of waste and safety is an integral part of the standardization process. Performance standards and expectations for predictable results are set.

A minimum of operational breakdowns is expected. Root-cause factors for operating problems are studied and largely eliminated on an anticipatory basis. Front-end prevention is the thinking. Methods to identify possible break downs and how to respond with minimal waste when they occur are a part of the standardization procedure. This makes work easier for maintenance personnel because they are exposed to fewer hazardous situations and jury-rigging because unusual work is not condoned. All involved understand that maintaining tight control over the management-of-change procedures is an integral part of the standardization element in 5S.

Sustaining what is accomplished in the four previous steps is the fifth step. According to the pharmaceutical firm, this is the most difficult step once superiority has been attained in the first four. It is expected that some workers may revert to previous practices, particularly with respect to cluttering the workplace and avoiding cleanliness. The concept can only be sustained by continuous management leadership. The CEO says that he knows he must continuously and personally embrace the 5S concept and both “talk the talk” and “walk the talk,” repeatedly. He holds his staff accountable for sustaining what they have achieved—an orderly and stable work environment in which efficiency is at a high level, waste is minimal, and hazards and risks are at an acceptable level.

When reviewing this article, one of the originators of the pharmaceutical company’s lean design process commented, “We have found that 5S is one of the foundations of lean. As far as safety is concerned, nothing makes hazardous conditions and practices stick out more than a well-organized facility. You should expand on 5S and how it can help improve safety performance.”

This premise required further study of how the 5S program operates in this facility. How well does it work at this location? Those involved say that the 5S program is an underlying reason for receiving numerous awards on employee safety, environmental affairs management and product quality. All 5S applications are not quite the same as what was observed at this location, either for lean or safety purposes.

Supporters of 5S who say that the concept can have a solid impact on worker safety contend that it is folly to expect good work practices and outstanding performance from workers if the work environment is dismal, messy and disorderly, and operational discipline is lacking.

Sorting, the first step in a 5S application, is to eliminate everything not needed to achieve an atmosphere of orderliness. When that orderliness is achieved in operational and storage areas—both for work in process and equipment needed to do the work—efficiency and housekeeping are improved, hazards and risks are reduced, and time wasted searching for work items is eliminated.

those agencies. Change control requirements applied by FDA are unique to pharmaceutical companies. They are the most extensive change control requirements the author has observed. This company maintains that strict concept for all of its change control systems.

At a senior management level, a change control document is produced that must be approved by all department heads. In ANSI Z10, the comparable requirement is to have a management-of-change process in place.

8) Project Safety Clearance & Lean Review

This is a summation step. The design document is reviewed by the SH&E group and the compliance group. These groups assess the need for further safety analysis of individual pieces of the process or because of their interrelationships. Safety specifications are expanded and become more specific.

Although lean considerations have been a part of this process from the beginning, application of lean concepts is stressed more rigorously at this stage by the project manager. The purpose is to error-proof, eliminate waste, have the process stop when the equipment recognizes a fault and avoid rejects. All or some of the lean systems defined (e.g., Poka Yoke, Jidoka, Kaizen, Muda) may be brought into play, but Muda concepts prevail throughout. Waste is to be at a minimum.

This company meticulously applies the 5S system (which the firm defines as sorting, simplification, systematic cleaning, standardization and sustaining), so 5S concepts are prominent in the lean process. A senior executive at this location noted, “If the staff has not been educated in 5S concepts and believe that their substance is a core value, you can forget about lean. You must have established a stable environment in which waste elimination is a fundamental to move into the next step to accomplish lean” (see sidebar above).

9) Drafting Vendor Specifications

Engineering department personnel draft vendor specifications although manufacturing, SH&E and operating personnel may also be involved. At this stage, communication begins with a selected vendor.
Subject-matter experts employed by the vendor may help to draft project specifications.

10) Conceptual Design Risk Assessment
This review occurs at the concept and drawing level. Formal risk assessment methods—qualitative or quantitative—are used as required. The risk assessments are documented and approved by a multifunctional team, of which SH&E personnel are a part. An independent reviewer who is not a part of the project team also must sign off on the risk assessments. Several people at this location have been trained to perform failure mode and effects analyses.

11) The Preliminary Design
Project team members work with the vendor to ensure that the users’ (in-house personnel) requirements are met. The receivables from the vendor include schematics, flow diagrams, drawings, further component specifications, and operating procedures and training manuals.

12) Value Stream Map: Waste Scavenger Hunt
A value stream map is initially created when the project is in the concept stage. At this phase, a flowchart that depicts the proposed design is created and reviewed. As noted, Muda encompasses all activity that wastefully consumes resources but does not add value. This waste scavenger hunt is designed to further minimize product defect possibilities, overproduction, excessive product handling, idle and waiting time by operating personnel and excessive inventory, while ensuring efficiency in processing and the best possible use of employee skills. All personnel levels are involved.

13) Proposed Design Safety/Risk Assessment: Create System Drawings
Now that a proposed design is available, additional risk assessments are conducted—before the system is built. SH&E staff are prominently active in these assessments as are other personnel. Use of formal risk assessment methods is more frequent at this stage. A final sign-off by the independent reviewer is required.

At this point, the design is frozen, and the vendor creates system drawings and builds to them.

14) Safety, Operational & Lean Review
At the vendor’s location, the purchaser’s SH&E personnel ensure that all safety-related specifications have been met before equipment is shipped. Factory acceptance testing is performed and reviewed by team members (representing engineering, operations, maintenance, validation, etc.) that the equipment operates as expected and that waste scavenger hunts are met. The project team, including SH&E personnel, must approve the installation before acceptance. The pur-}

15) Standard Work Procedures
In reality, this function is conducted in parallel with the previous steps. It involves writing standard operating procedures, developing training modules, defining recordkeeping needs, drafting production records and related issues.

16) Facility Review & Approval
After installation, in which the vendor is extensively involved, site acceptance tests are performed. The project team, including SH&E personnel, must approve the installation before acceptance. The purpose is to validate that the equipment performs as intended, that the quality level expected is achieved and that SH&E specifications have been met.

17) In Production
At this stage, Kaizen (continuous improvement) is a governing concept. Superior quality is maintained. Adherence to standard operating procedures—including safe practices—is the norm. Waste is constantly sought and eliminated.

18) 5S Review
Since this organization has made applying the 5S system a core value, a final review is made to ensure that all of its elements (sorting, simplifying, systematic cleaning, standardization, sustaining) have been maintained.

Conclusion
Because of the base on which lean concepts have been built—the idea of removing waste from a system—applying the concept likely will have staying power. Since accidents and their consequences are so fundamentally wasteful, preventing them should be an integral part of lean applications.

From the beginning, when an organization initiates discussion of adopting lean concepts, safety professionals should step forward to become members of the lean team. This presents an opportunity to address hazards and the risks that derive from them in process design and redesign so that acceptable risk levels are achieved. To do so, safety professionals must become familiar with lean concepts.

References