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Kaizen Effectiveness and Execution Strategies

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KAIZEN EFFECTIVENESS AND EXECUTION STRATEGIES

by

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ABSTRACT

As technology and the educational levels of employees increase, companies typically benefit from the new applications or methodologies introduced into their organizations. A common constraint that causes many companies to lag behind the competition is the amount of waste within their organizations. Companies can have the best technologies and ideas, but if the way that they implement them is not efficient, they will continue to throw money away even if they do not realize it.

Lean manufacturing has been the answer for many companies that have experienced a history of waste. This paper discusses the broad picture of lean practices and the rapid change events, also known as kaizen events, used to implement lean improvements. The various tools used with kaizen are described in great detail and examples of how each can be incorporated are covered. Actual kaizen events are outlined and the forms used within them are provided. This paper will provide guidance for young manufacturing engineers or those new to kaizen and its lean implementation strategies.

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INTRODUCTION

PURPOSE

This paper is structured in a way to be used as a tool for someone unfamiliar with lean practices and kaizen activities. People whom this paper would benefit include, but not limited to, recent graduates entering the work force as manufacturing engineers or engineers looking to use the methodologies of lean manufacturing through the use of kaizen events. The information within this paper which was gathered through research and experience will expose the readers to various types of industry waste in order to reduce or eliminate them.

BREAKDOWN OF THE PAPER

Here are brief descriptions of the chapters that follow:

Chapter 2 provides background of kaizen so that readers have an understanding of how it has evolved.

Chapter 3 discusses various tools used in conjunction with kaizen events. These tools are described in-depth and examples are given for each.

Chapter 4 discusses lean manufacturing and the focus to eliminate waste. The various types of wastes are described and examples provided to help the readers relate to them. The 14 principles of the Toyota production system are discussed to give a broad picture of the lean methodologies.

Chapter 5 shows how real life kaizen events can be structured and what types of activities take place. There are many photos included to help the readers get a feel for what ideas are generated during such events. The kaizen events discussed are that of 5S and 5P events.

Chapter 6 describes how kaizen events are too often focused on the production floor. The mentality of kaizen is for continuous improvement, so this chapter explains how it is applicable to the office areas to promote improvement activities. Most people would agree that there are plenty of wasteful activities going on at the administrative level. This chapter provides examples so the readers will also pick up on them and avoid falling victim to them.

Chapter 7 is the conclusion and reiterates the major points of the paper. This chapter emphasizes the big picture of what is important for kaizen events to be successful. It involves promoting a culture that is accepting of the lean initiatives and has clear objectives of what need to be done to improve. Chapter 7 also mentions how important it is to stay on task and revisit past areas to ensure that the improvements are sustained.

Chapter 2

BACKGROUND OF KAIZEN

KAIZEN HISTORY

Kaizen is a tool or methodology which originated in Japan by the Toyota Motor Company and translates to English as continuous improvement. Kaizen's direct translation is good change coming from its Japanese roots *kai* which means little, ongoing and change. *Zen* means for the better or good [3]. In the early 1960s, Shigeo Shingo introduced the concept of zero quality control (ZQC). From his ideas, in 1962, Tetsuichi Asaka and Kaoru Ishikawa developed quality circles which resulted in the first real kaizen events [4].

Kaizen events or blitzes consist of cross functional teams typically of 7 to 15 people and focus on accelerating improvement activities over a duration of about 5 days. They are usually used in a manufacturing setting with the purpose to eliminate non-value added activities to reduce costs, improve quality and implement one piece flow through a pull system. Incremental changes are achieved over time even within the same focus area such as a product line if similar kaizen events are repeated. Additional improvements are typically discovered, hence the name continuous improvement. Kaizen events unlock the talents and abilities of employees, allowing decisions to be made at the lowest levels of the organization. Removing the barriers of ranks within an organization allows the group to be confident enough to voice ideas to the problems at hand without worrying how a member of the senior staff may respond. Kaizen is often thought of as a specific activity which focuses on change and occurs during a particular event. This can be true, but it is more accurately thought of as something that is ongoing. We should always be looking to improve ourselves and our surroundings; this is the mentality of kaizen. It is not necessarily a specific event, but an approach for improving efficiency and effectiveness.

Various events took place leading up to the formal practices of kaizen. During World War II, the U.S. military established a program called Training Within Industry (TWI). This focused on improving productivity by eliminating wasteful practices and incorporating operator involvement. The program promoted standardization in order to maintain repeatability of processes. After the war, there was a massive reconstruction of Japan which was aided greatly by the United States. With different systems like TWI and the methodologies of great people like W. Edwards Deming, Frederick Winslow Taylor, Walter Shewart, Joseph Juran, and Frank Bunker Gilbreth, the Japanese had a springboard for bouncing into restoration efforts on the right foot [1].

Kaizen is one of the many tools used in the implementation of lean manufacturing. Although it has existed for decades, many companies are still not adhering to the lean practices; consequently they continue to be wasteful. Lean has been increasing in popularity in recent years as companies fight to stay competitive.

Lean is now spreading beyond the realm of manufacturing and is gaining popularity across other areas such as service industries. This is largely because change is more accepted in recent years as a result of increased competition, technology and educated individuals.

Chapter 3

TOOLS USED WITH KAIZEN

Concepts of the Toyota Production System are strongly followed by many industries. Many of the TPS tools used during kaizen events will be discussed within this chapter. Again, they all center on the topic of lean by improving efficiency and productivity, thus reducing costs and increasing profits [13].

5S

A good kaizen event to use as a starting point is that of 5S. This activity can be thought of as spring cleaning. It involves tidying a given area and getting rid of unnecessary items that simply take up space. The components that make up 5S are sort (*seiri*), straighten (*seiton*), shine (*seiso*), standardize (*seiketsu*), and sustain (*shitsuke*) [1, 15]. Other words that can be substituted in the 5S methodologies are simplify, stabilize, scrub, schedule, score, and safety [1, 2]. A 5S kaizen event which was co-lead by the author and executed at a medical device manufacturer is covered in Chapter 5.

Sort (seiri)

Sort involves removing any unnecessary items from an area to minimize clutter. People too often get used to items or equipment sitting around even if it is not used. These items are simply a waste of space.

Straighten (seiton)

Straighten involves putting everything in its place. Examples of this may be implementing shadow boards for tools or labeling and taping off areas for specific items. This allows someone to see if anything is missing from an area with a quick glance. If something is not located in its designated area, it needs to be located. Similarly, if something is in an area and does not have a place designated for it, it may not need to be there.

Shine (seiso)

Shine is the cleanliness step that helps expose problems. If a work area and its equipment are always kept clean, it will be more obvious when something is wrong. For example, when an oil leak is observed under a press it is signaling the problem that a seal or other item is malfunctioning. This will allow for quicker reaction time than if the area was filthy.

Standardize (seiketsu)

Standardize is the step that helps keep the previous three S's under control. It is the implementation of systems for setting rules that each area must follow such as scheduled cleaning programs or what types of identification should be used to outline equipment in each area.

Sustain (shitsuke)

Sustain is typically the most difficult step as it involves maintaining a stabilized workplace going forward. This is done by having everyone trained on the prior four S's and practicing them properly. This step is often tracked over time by having audits. It provides visibility to areas that begin to lag behind with the 5S program so that the problems can be addressed accordingly [1].

FIVE WHY ANALYSIS

Five why analysis involves asking "why" multiple times in order to get to the root cause of a problem. Too often, problems are assigned corrective actions which are more of a band-aid fix than a permanent solution. The true root cause needs to be discovered before the problem is properly addressed. A basic example could be someone fixing the problem of a flat tire that blew out while driving. Someone may simply put on the spare tire and proceed with the drive. Someone else may ask why this occurred and investigate, finding a nail which would then prompt them to check the other wheels or maybe their driveway for nails if construction was done on their house recently. Another detail oriented individual may notice the irregular tire wear and ask why this is present. They would determine that the air pressure was incorrect or that the suspension was the true root cause to the tire wear that lead to a blown tire.

This could possibly go even further by asking why again and discover that the tire pressure was incorrect due to the missing valve stem cap or the suspension was a problem because of a bad seal in the shock. Similarly, when scrap rates increase in production environments it is very important to get to the root cause of a problem and address it as soon as possible. This will prevent future scrap and downtime common to troubleshooting or firefighting.

In addition to asking why multiple times, there are also statistical tools that can be utilized for determining the root cause of a problem. These tools are check sheets, histograms, pareto analysis, scatter diagrams, process flowcharts, cause-and-effect analysis and run diagrams [8, 10].

POKA YOKE

Poka yoke, also known as mistake proofing, is another extremely valuable tool that needs to be considered to prevent problems [16]. This is the concept of making it impossible for problems to occur usually through product design or tooling. A very basic description would be to make a round hole and a square hole on the top of storage bins to prevent round and square parts from getting mixed. Poka yoke is implemented at the design stage of most products and processes. Another example could involve two parts that snap together. If it is desired that they only snap together one way, the remainder of the product would need to be designed to not accept the mating part otherwise. An example of this was done by the author when fixturing components to be ultrasonically welded. There were many tabs for a part number that were very similar. Pins were added to the tooling that would only accommodate the correct parts for an assembly.

A spin off of poka yoke is the method of jidoka or autonomation which occurs when equipment is automated in the sense that it can detect the presence of a defective part [9]. This was used by the author to sense the orientation of very small products before they were welded together. The method used was that of a vision system which had a set area programmed to known geometry. If a part was out of position the camera would not recognize the part features and would not cycle.

SMED

Other practices involved in kaizen could be SMED or single minute exchange of dies. This promotes simplified changeovers to reduce set up times. It involves transferring activities that are internal set-up tasks to be external tasks, therefore preparation activities can be done while the machine is running [17]. An example of this would be the task of staging the next mold to be run on a press. This can be done while the prior job is still running. To minimize downtime, it is critical to perform as many activities as possible before shutting equipment down for changing over. Once the press is shut down everything should be available for the changeover to occur.

One step further would be to design the process to be SMED friendly. This could involve replacing many bolts with a simple T-slot and locator pin for tooling. Once loaded, it would already be in position. Making standardized base plates for tooling to be run on the same equipment helps reduce changeover time greatly. A growing method to reduce set up times is the implementation of magnets for tooling and work-piece holding. This can help reduce set up times drastically by utilizing magnetic forces to hold items in place instead of clamps [5].

TPM

Total productive maintenance is the formal plan for maintaining equipment so that it always operates as designed [11]. In theory, equipment should not experience unscheduled downtime if TPM is followed properly. With total productive maintenance, operators are responsible for daily tasks such as cleaning, monitoring performance and making minor adjustments to ensure consistent operations of equipment. TPM benchmarks a machine's efficiency by calculating the overall equipment effectiveness or OEE. OEE can be calculated as seen below:

$$Oe = Ma \times Mp \times Qr$$

where:

Oe = Overall equipment effectiveness, %

Ma = Machine or equipment availability, %

Mp = Machine or equipment performance rate, %

Qr = Quality rate, %

Machine availability (Ma) is calculated by:

$$Ma = (Ar - Da) / Ar$$

where:

Ar = Required availability to hit production requirements (min or hrs)

Da = Downtime including set ups, scheduled and unscheduled downtime

Machine performance rate (Mp) is calculated by:

Mp = (Ct x Mo) / Ot

where:

Ct = Ideal cycle time (pieces per hour)

Mo = Machine output (parts per period)

Ot = Operating time (min or hrs) = Ma

Quality rate (Qr) is calculated by:

Qr = (Pi – Pd) / Pi

where:

Pi = Number of parts input to the process

Pd = Number of parts output as defects

Rate Efficiency

RE = Actual Production Volume x Actual Cycle Time) / Actual Running Time

Speed Efficiency

SE = Design Cycle Time / Actual Cycle Time

Performance Efficiency

PE = RE x SE

If SE cannot be found for whatever reason, PE can be found as a function of lost time from interruptions.

PE = (Actual Running Time – Time for Interruptions) / Actual Running Time

The overall effectiveness goal is to achieve at least 85%. The author has not yet observed a company accomplish this goal, although it is very possible for a robust process [4, 8].

HEIJUNKA (PRODUCTION LEVELING)

Heijunka or production leveling is enforced to balance the assembly lines. This allows for smooth product flow in addition to reducing fatigue and boredom of operators. If the operators are stressed in the morning because they were told to hit high production volumes they will likely fatigue. It is also likely that quality will be sacrificed due to the increased urgency and instructions to rush. However, if they get caught up and do not need to work as hard in the afternoon, they may get bored and not pay attention to what they are doing. This can also result in loss of quality. It is the responsibility of supervisors and members of the scheduling or supply chain team to make sure manufacturing is balanced as best as possible to still meet demand.

ANDON

Andon involves setting up a method for signaling problems. Common examples utilize light beacons and alarms to inform people that an error has occurred [6]. This allows the problem to be addressed quickly before the situation gets worse. The molding presses previously used by the author would alarm if they experienced a problem. An example could be the mold dies closing up on a product thus sensing the irregular force at an unclosed condition through the use of a load cell. Once alarmed, the press could then be inspected for damage before further production of more components. Historically, a core pin or ejector pin could have broken off and would not have been observed until hundreds of parts were already made. A manual andon is used at the author's current employer on a few product lines as the result of a kaizen event. The actual andon is an orange tip-up used for ice fishing. This is basically a flag that is triggered by an operator if there are problems on a production line. This is a visual aid for a technician when he approaches the room to see which line to address for maintenance related items.

Chapter 4

LEAN AND THE TOYOTA PRODUCTION SYSTEM

LEAN OVERVIEW

As discussed in earlier chapters lean manufacturing has been a growing practice for years. Digging deep into the study of lean and the Toyota Production System, one will find that the purpose is to eliminate waste [18]. Depending on the sources, there are typically seven or eight types of waste. They are defects, excess inventory, unnecessary transport, time waiting, overproduction, processing, and motion. An eighth waste that can be considered is that of unused employee creativity [1].

Defects

Defects include any product that does not meet specification and must be rejected. This also includes product that goes through rework operations in order to be salvaged.

Excess Inventory

Excess inventory is any abundance of raw material, work in progress (WIP) or completed product. Having excess of any of these does not create revenue for the manufacturer so it does not add value. Storing these items leads to losses due to damage, obsolescence and costs incurred due to storage and transporting the materials. Allowing excess inventory creates issues because it does not allow problems to surface. For example, if a machine is producing a large amount of scrap, it may not be caught immediately due to the buffer of inventory that is ahead of that defective product. Using one piece flow, problematic situations are discovered much sooner as there is less product in queue to be inspected.

Unnecessary Transport

Not only is inventory a large waste of resources, but transporting it to and from operations is also a wasted effort. This was observed by the author at a prior employer where product was injection molded at very large quantities and stored. The components would be removed and processed through various operations and shelved again. This required a lot of resources to transport the product to and from workstations, not to mention the efforts that it took to disposition the parts each time.

Time Waiting

Time spent waiting is a significant problem as it does not add value to the product or service. It is especially a problem when some operations are very labor intensive and others have excess slack time. This is where heijunka or production leveling came into play in Chapter 3. Other examples of wasteful time waiting could involve waiting for parts that need to be delivered in order to proceed with an operation, equipment downtime and variances in operator capabilities such as speed.

Overproduction

Overproduction is naturally a waste due to producing inventory for which there are no orders yet. It necessitates additional resources such as staffing which would not otherwise be required to meet the actual demand.

Processing

Processing is a good thing if utilized properly. Where it becomes a problem is when processing is not necessary, such as producing products that have far superior quality than is required for function. For example, if a washer is required under a bolt and nut that hold a garbage can together, it would not be necessary to have specifications of ±0.0001" on the dimensions. This adds additional costs that are not appropriate for this application. Processing waste is typically a result of poor product of process design. An example that the author had addressed involved the cleaning of products. There was a 45 to 55 minute cleaning process in place that was not optimized. The author changed the solution and reduced the time down to 15 minutes. Much of the time in the previous method was not value added.

Motion

Unnecessary motion involves non-value added movements such as an operator reaching across their body way above their head for something that could be placed appropriately near them. Another example of wasted motion could involve looking for parts or tooling that is not stored in an efficient manner. At a prior employer of the author, there were cabinets that stored the end of arm tools (EOAT's) for the robots in the rear of one room. The technicians would walk great distances in order to get the tooling required for a particular set up. Over time, there were additional cabinets added to other rooms to hold tooling used in the given rooms. This decreased the amount of unnecessary walking experienced by the technicians on an hourly basis.

Unused Employee Creativity

An unfortunate waste stems from the lack of communication with employees. Many of the good ideas for change come from the people that the change would affect. A common example would be for production operators to think of better ways to do their jobs. This is not a surprise because they spend all day performing the tasks; naturally they want to find the best possible method for doing it. It is a problem when engineers or management do not listen to the creative ideas generated by the employees. This is where participative management comes into play. This involves empowering the employees to make decisions and promoting a culture which is open to suggestions from people at all ranks.

THE TOYOTA PRODUCTION SYSTEM (TPS)

As described above, lean practices drive to eliminate wasteful activities in every form that it exists. The Toyota Production System works to achieve this through many practices, each of which is described in great detail in The Toyota Way [1]. The 14 principles and examples are described below.

Principle #1: Base Your Management Decisions on a Long-Term Philosophy, Even at the Expense of Short-Term Financial Goals

The big picture that controls how a company operates relies on the culture. It is important that the overall philosophy and beliefs of upper management is communicated and understood by the rest of the organization.

Toyota shows time after time that it has strong values that it has stood by over many years. The mission statement of Toyota expresses the passion that they have to please the employees and the community. If both of these are taken with high regard then it is likely that Toyota will benefit long term from its investment in its people.

Another belief that exists at Toyota is that they do not focus on saving money today. They are more concerned that the long term milestones get achieved as the company grows. Again, if they prove to their employees, their communities and the rest of the world what a stable, high quality, customer driven company they are, Toyota will win more loyalty over the years. Toyota has proved many times that the customer is the number one priority. During the "Nixon Shock" of the early 1970s there was an import tax imposed that caused prices to vary on vehicles coming into the country. When this surcharge was reversed Toyota stepped in and proved its dedication to its customers. Toyota paid the extra taxes that were charged to the dealer and customers. This was a large financial burden to Toyota, but it helped gain the respect of many happy customers.

During difficult times, companies often need to cut costs in order to hit targets and keep financials up. One specific example involving GM was when they shut down a plant that had been excelling for a period of time. This type of action presented a picture to other GM employees that even if you perform up to expectation, you may still lose in the end. This is a significant way a company could lose the trust of its employees. Toyota on the other hand has moved people around when they were not needed in a specific area. One such example was when they put "extra" employees onto kaizen teams rather than laying them off. This dedication to employee development has proven to be effective. During the building of the NUMMI plant, Toyota sent many of the leaders to Japan to examine the TPS practices in action. They were then converted to operate in a similar manner as that of Toyota in Japan. When the NUMMI plant reopened in the early 1980s they surpassed all of GM's plants in North America.

The author of this paper has observed instances where struggles with culture lead to problems with moral. Over time, that decline in moral lead to a higher turnover of the employees. Once a few people quit, it turned into a chain effect resulting in people resigning almost every week for many months. The problem magnified when the new hires were almost entirely hired from the same company that the new directors and president came from. The negative feelings then grew as the "new regime" took over. A similar situation happened when Daimler bought out Chrysler. They stripped Chrysler of its culture that it had been working on improving. In order for a company to succeed it needs a strong base which is the long term philosophy and actions that it communicates to the employees.

Principle #2: Create Continuous Process
Flow to Bring Problems to the Surface

The main point of this principle is to streamline operations in order to shoot for processes that allow one-piece flow, or as close to it as possible. This mentality of not producing something until it is needed greatly reduces inventory. With inventory forced to low levels, it makes possible the ability to see problems that exist. Too often problems go unseen as inventory acts as a buffer, preventing problems from arising.

Traditional mass production practices group similar machines and similar people together into departments. At a past employer of the author, the facility was divided up into "bays" for each type of process. Three bays were made up of the molding machines, one large bay contained all of the Swiss machining centers and another bay contained the secondary operations. The typical flow started by molding many components and stacking them in totes on shelves until the next operations were ready to take place. It could possibly be the same day or maybe weeks later that the parts would be worked on to fill the orders. The remainder of the product would then go back on the shelf. There were a few operations that involved an operator working at the molding machine performing tasks. Very rarely would they perform all of the required tasks for the part to be ready to ship.

This practice was also done in the office areas. All of the quality engineers sat in a group, similar with the designers, manufacturing support, sales, technicians, and all other functions. This is nice for tasks like brainstorming and conversing about projects. As a contract manufacturer this layout worked well as there were not many large product lines requiring work cells.

The current employer of the author handles this in a much different way. Operations are split up into value streams, each supporting a specific family of products. Each value stream has its own equipment dedicated to its processes. The same is true for the people in the office area. All of the people associated with each value stream sit in cubes grouped together. This consists of the engineers, supervisors, technicians and the manager.

With respect to product flowing through the area, this did not exist when the author began working there. When the author started in the end of 2005, the value stream had recently moved from another building and everything was randomly stuffed into a small area. The product routed throughout the area with absolutely no formal flow in place. This was a concern not only for efficiency, but largely for lot segregation which is very important in the medical industry. The author's first project was to expand the area into a nearby space and create more structured flow.

Principle #3: Use "Pull" Systems to Avoid Overproduction

It is very common for manufacturers to operate in a manner that pushes product through the fabrication areas. This creates problems of excess inventory as a result of bottlenecks. While working for a prior employer, the author observed large quantities of components getting molded and set aside until the mating parts would be molded. Then the component would be assembled at a later time. Producing in large volumes may have been chosen due to the very long times required for changeovers.

There is an example in the Toyota Way [1] which stated that we do not gas up our cars per a schedule; if we did we would run out some weeks and only need a few gallons other weeks. This is the result of unpredictable demand. Rather, we simply fuel up our cars when the car needs gasoline. This is similar to a production line where product is taken from the previous step when it is needed. The concept of a pull system was used on a few assembly lines at the previous employer of the author. The method of having in-process kanbans was very useful. Continuous flow was difficult as the cycle times at the various operations were not the same. These steps were done in batches of five parts where the operator would only work on the parts in the queue just upstream to them. If an operator caught up at a given operation, they would rotate to another operation to keep product moving. In order to set up a line like this, it is very important for the operators to be cross-trained.

The author investigated the implementation of a pull system throughout the product lines at his current company on prior products, however, there were constraints preventing it from occurring completely. The operations are very uneven and some operations need to be batched. An example of batching involves cleaning many products at a time. Due to the relatively long cleaning time it is necessary to batch process at that operation to prevent capacity problems.

Principle #4: Level Out the Workload
(Heijunka)

In the perfect world, all companies would be completely lean with stable schedules and no inventories. In reality, true lean manufacturing is very difficult to follow exactly because of the unknown factors that affect production. It is common that customers' orders are different from week to week which causes a problem with continuous flow. Suppliers may not be able to supply resources at an even pace and demand may have spikes that cause rush orders that stress the system to meet the needs of the customers.

Although demand may be uneven, that does not mean that production should be. If products were manufactured to follow the customers uneven demand there would be days where resources are underutilized while other days they would be overwhelmed, working overtime. Taiichi Ohno mentioned the preference to be like a tortoise in a race rather than a rabbit. Similarly, a slow steady production workload is more desirable than a fast jerky one where the system is under pressure at times and idle others. Companies should try to focus on leveling out workloads with respect to both volume and product mix, or leveled mixed-model production. This mix allows various products to get produced over a short period of time rather than a lot of one product. If large quantities of each product were made before doing a changeover inventory is created and then there is a risk of holding onto unsold goods.

The author held a job while in high school which was an industrial sized laundromat where multiple truck loads of sheets, table linen, and uniforms were processed everyday. When a customer would call for a rush order of various linens, the laundromat had to react accordingly. Rather than running a few hundred pounds of single sized linen, or a single color of cloth napkins, it was chosen to process smaller quantities of various types of linens in order to meet the various demands.

A similar example involved a job the author held while in college which was a dishwashing position at the cafeteria. During peak times, dishes and silverware would run low as the conveyor washing machine would only run so fast. The author found that processing a mix of dishes such as small quantities of each item was the best method for keeping the cafeteria supplied. This solved the problem of availability caused by washing large numbers of one item while the other dishes would wait to be addressed. This goes to show that even in the most basic environments, the mentality of level work loads and product mixes serve a purpose.

Although inventory is looked at negatively, it is helpful to have some on hand to even out the work load and absorb the shock of unexpected orders. However it tends to be cheaper to allow inventory of raw materials rather than finished goods.

Principle #5: Build a Culture of Stopping to Fix Problems, to Get Quality Right the First Time

This principle focuses on saving time and money by doing things correctly the first time around. The old way of thinking was to hurry up and make product with a focus to keep the machine running. If there was an issue, the products could simply be reworked.

In more recent years people understand that the resources put into rework or even scrap for that matter can add up quickly so it is much more efficient to address issues as soon as possible to minimize the costs associated with it. Another lean practice that works in line with this mentality is to minimize inventory because it allows defects to surface more quickly. At one time the author was looking to batch-process the very time consuming process of cleaning his products. After closer consideration it was determined that this would be a very bad idea as the lasers cut the stents at a relatively slow speed. This would cause the operators to wait a long period of time before the cleaning process could be executed. Another issue would be the potential of building many defective parts as they would not get inspected until many are already produced. Minimizing the work in process allows problems to surface more quickly, thus feedback can get back to the laser technicians as soon as possible.
As mentioned in Chapter 3, andon is the ability of a person or equipment to inform others that there is a problem that needs to be solved in order for processes to operate correctly. Machines often have light beacons or alarms on them to signal when something is not functioning properly. This allows a maintenance technician to quickly address the problem.

Another topic covered in Chapter 3 to maintain quality is poka-yoke. As discussed previously, this deals with creating processes/equipment that is mistake proof. The author has designed and built many fixtures for assembling, salvaging, welding, crimping, etc so that they could only be used in a specific fashion. If an operator accidentally tried to assemble a product incorrectly, the fixture would prevent that from occurring. Another method that the author has practiced greatly is the use of digital photos in the manufacturing procedures that the operators follow. Some tedious operations really benefit by having visual aids to help explain what's going on.

Principle #6: Standardized Tasks Are the Foundation for Continuous Improvement and Employee Empowerment

Years ago before standardization was a common practice, supervisors had the mentality of trying to get as much productivity that they could out of their workers. This may be beneficial for a piece-work type of situation where quality is not of importance, yet it is not a good way to think in the manufacturing world. Operators would be judged against predetermined cycle times that they would have to meet. This lead to operators withholding "tricks of the trade" that they may have learned in order to have an advantage. If the operator's tricks or creative ideas were discovered, the expectations would be raised and the operators would need to work even harder.

A more appropriate method for structuring operations is to have a standardized process developed for all tasks performed in production. This begins by determining the takt time which is the rate of customer demand, or units per period of time required to satisfy the orders. Then the sequence of the specific processes and the stock required are determined in order to set up the standardized work. To develop standardized work, the goal is to determine the best method possible to complete the given tasks. The best operator should be observed for quality and time that it takes to perform the operations. This "best" process should then be documented and trained across all of the operators to ensure that the work will be consistent for all people. When setting up standardized work it is very important to get feedback and advice from the people that will actually perform the work. They will accept the new or changed process more readily if they had input into its implementation. In addition to that, they will most likely have ideas from their perspective that the engineer did not take into consideration.

Standardizing tasks helps create predictable processes which help scheduling jobs and estimating lead times. This also helps relieve stress of operators by having everything done the same way rather than everybody doing their own thing and having variation in products.

Once a process is standardized, it should not be forgotten and left to simply run unobserved. As problems arise and as the operators gain experience, they may come up with ideas for improving the processes even further. Also, new technologies may be developed that could be implemented into the process. Processes will need to be updated and documented, so it is important that all changes are communicated to the employees. All of the affected operators should sign off on the most updated revisions for all of the standardized procedures that they perform.

When implementing standardized work it is important to find the balance of creating procedures that provide direction while at the same time allow the operators to have the freedom to be creative to meet targets consistently.

Principle #7: Use Visual Control So No Problems Are Hidden

All companies need to be organized in order to run efficient operations and a clean appearance is often a sign that a company is well run. Disorderly environments tend to cause problems especially in the manufacturing arena where tooling, fixtures, equipmen,t and supplies need to be located quickly to keep productivity high.

As discussed in Chapter 3, the system of the 5S is important as it focuses on the stages of spring cleaning to remove unnecessary items and make the required items visibly labeled. Similar to the shadow board method to show visibility of tools, the author created custom racking used to replace shelves in cabinets. These racks held the robot end of arm tools in order to give each one a home and prevent them from piling up.

With respect to visibility in the office at a managerial level the author experienced the use of a "war room" while working for a past employer. This was a large room with white boards hanging on all four walls used to track and discuss the previous day's productivity. The amount of orders shipped on time, dollar amounts, and status of continuous improvement projects were updated and scrap issues were also discussed. Another previous employer of the author utilized a real time monitoring system that could track the status of all of the presses on the production floor from any computer in the company. This did not save money, but it was useful for people to monitor the equipment and know when problems were present.

Principle #8: Use Only Reliable, Thoroughly Tested Technology That Serves Your People and Processes

Technology should only be implemented for use after it has been proven out through vast experimentation involving a broad cross-section of people. If it cannot be verified that a technology will truly be an improvement over existing processes, it would not be worth pursuing. It is important to include a variety of people in the trials, from hourly operators to engineers. The multiple sets of eyes will see different aspects of the technology and how it will affect the various groups. It is also wise not to rush new technologies that people are not familiar with. This rapid transition will likely frustrate the people working with the new technology and tend to make it difficult for them to accept the new changes.

The author had an experience with implementing a new technology while supporting some implantable component product lines. The products consisted of a molded housing containing multiple metal blocks that lead wires would insert into. The lead wires were then held into place (by the surgeon) using set screws. Some companies used a design that consisted of metal retainers that get welded over the set screws in order to ensure that they do not back out and become loose in the body. It was required to verify the weld strength of every retainer before it was shipped. This was done using a torque wrench to back the set screws up against the retainers at a specified force. This operation was done manually for years until finally the customer agreed to supply a semi-automated unit that would torque the set screws using a programmed controller. This unit was rushed to our facility and management was determined that it must be implemented as soon as possible. The author of this paper reprogrammed the equipment to perform beyond what the customer was aware the unit could do. There was little time to spend on the validation and training of employees, so these efforts were rushed as well. It was a very "touchy feely" operation so there was a learning curve that the operators had to go through until they felt comfortable with the process. The problem was the equipment was released to production and the operators started using it with very little experience. This expedited transition lead to disgruntled workers and high scrap rates. The author finally went back and made fixture changes in addition to spending more time with the operators. The yields then went from about 50% to 95%.

It was discussed in The Toyota Way [1] that Toyota often designates a pilot area to test and implement technology. The process can then be closely monitored and issues can be addressed before getting released to production.

Principle #9: Grow Leaders Who Thoroughly Understand the Work, Live the Philosophy and Teach It to Others

Only when the leaders at the top of an organization have a clear picture of what the objectives for the company should be can the rest of the organization then follow suit. It is known that companies often go outside of an organization to fill high power positions such as that of a CEO. This seems to be desirable if the candidate has a proven track record, especially if their background is from the same industry. If that is not the case it may be difficult for the new leader to get a quick feel of the company culture and philosophy.

Toyota tends to groom its leaders for many years and build them up to high attaining positions. If a leader cannot demonstrate the ability to understand how work gets done at the production floor level, they will be ineffective in there decision making. A large reason that Toyota chooses its leaders internally is because this keeps the culture consistent through the transition of the change over. Companies that switch CEO's may struggle if there are radical shifts in the corporate culture. These high level shifts make it difficult for the employees to achieve a sense of direction that allows them to focus on their paths and learn.

Toyota also preaches "genchi genbutsu" or going to the source and understanding the situation. They take pride in having many of the leaders groomed and promoted through various positions, gaining vast experience on the way. It was stated that president and CEO of Toyota Motor North America Toshiaki Taguchi started as a freshman trainee, going through various operating departments. He even spent about 5 months at a dealership where he was required to go door-to-door carrying brochures promoting his vehicles.

A distinctive philosophy present at Toyota is the managerial approach to the organization. Some companies lead from top-down which does not take into consideration the people at the value added operations as much as they should. Toyota focuses on a bottom-up management style that concentrates on the people who complete the tasks at the shop floor and develops them so that they can make the right decisions on their own.

The phrase "Before we build cars, we build people" says a lot for the focus and long term vision of Toyota and its employees. It goes to show that Toyota has made the connection with happy, well trained, motivated employees as they have been extremely successful. Companies that focus on products first may not have buy-in of the employees on various programs. If an employee does not believe in a methodology or understand company objectives and priorities, they cannot complete their job as effectively.

Principle #10: Develop Exceptional People and Teams Who Follow Your Company's Philosophy

An expense which a company must deal with that is often overlooked is that of employee turnover. High turnover is typically caused by poor benefits/compensation, lack of direction, motivation, and inferior work conditions. In addition to being satisfied with lower level needs such as pay, people need to enjoy themselves and a large part of what makes a company enjoyable is the culture that exists. As Toyota has demonstrated, they put a lot of time and effort into creating a culture that will support their production system.

An important factor in building a successful business is the selection of applicants to fill the positions. Toyota has been known to take a year or two to extend offers to potential employees. Although that may be excessive, this practice of playing it safe is crucial. If a person is hired quickly there is a good possibility that the individual may not be right for the position. This can be an expensive process if the new hire is unproductive and eventually quits. The company must then begin the hiring process all over and try to make up for the lost time.

Once the correct employees are in place, Toyota focuses on forming the workers into functional teams. The teams start with the shop floor associates who perform the value-added jobs. Next are the team leaders whom support the shop floor workers by covering absenteeism, replenishing materials to the line, ensure standardized work is followed and various other hands-on activities. Above the team leader is the group leader. They coordinate process improvement projects, cost reduction projects, vacation planning, monthly production planning and similar managerial tasks. Leaders at Toyota are very hands on and it is said that there is always a mentor available to support day-to-day work.

It is beneficial to have hands-on leaders so they have a clear understanding during discussions of technical topics. If a high level manager has high expectations for a given project and does not understand what technical resources will be required, the support staff will likely get frustrated by the unrealistic goals.

A very crucial aspect of building successful teams is how the employees are motivated. If a person has no drive to complete a task, it is unlikely that the task will be completed at its full potential. It has been said that the lower level needs of Toyota employees such as good pay, job security and safe conditions are covered sufficiently.

So the leaders focus on building a culture that promotes the use of challenging work to build self-confidence and reach self-actualization.

Employees at Toyota are happy because management focuses on the needs of the people. Due to very desirable awards that are offered and an enjoyable work atmosphere, 60% to 70% of the employees attain perfect attendance. The people feel they can trust the company and the company trusts and respects the employees. Another amazing statistic is the fact that one Toyota plant recorded 80,000 improvement suggestions in a year and implemented 99% of them. This goes to show that the employees care about the success of the company [1].

Principle #11: Respect Your Extended Network of Partners and Suppliers by Challenging Them and Helping Them Improve

Something that proves Toyota has reached the highest level of the lean enterprise is that they are committed to learning and growing together with their suppliers. This goes to show that Toyota is a model company for supplier relations. To get to the level of focusing on improving suppliers in order to improve productivity shows great dedication. If the supplier is inefficient in its processes it may be charging unnecessary prices for the products. After helping a supplier improve the way they operate, their costs will be reduced which will lead to reduced costs for the end user.

Toyota is known for being a great customer although a challenging one. Toyota has the mentality that they would be disrespecting a supplier if they were too easy on them or if they did not teach the supplier ways to make improvements. This is true in the sense that if a company does not help improve its suppliers, they must not have respect for their own company either since suppliers are almost an extended branch of the immediate company.

Years ago Toyota learned that it was important to find solid suppliers that could grow with the company long term. There were times when production would be down all day due to lack of quality parts. In the present industry, suppliers must prove their commitment to Toyota's high standards and expectations. Often they run small orders and ramp up to larger orders as they demonstrate competency. American automakers do not have the same reputation of working with suppliers. One example involves an automaker pursuing a program for supplier development. Before long, feedback was received by the suppliers stating that the automaker should focus on internal processes before addressing the issues of its suppliers. This would be a harsh blow, but a reality check at the same time.

An example of making improvements outside of the company walls deals with the logistics of receiving components in a just-in-time manner. Ideally a company does not want to have large sums of inventory lying around taking up space. Toyota teamed up with an outside service to avoid making infrequent bulk orders. A practice called cross-docking was implemented which involved parts getting reconfigured at the services location and shipping the desired product mix to the factory frequently. This allows parts from distant suppliers to be delivered often from the closer cross-dock.

Eventually Toyota set up formal organizations for teaching its suppliers. One example is BAMA or Bluegrass Automotive Manufacturers Association which was started in Kentucky area. Another was started in 1968 by Ohno which was called OMCD or Operations Management Consulting Division to improve operations in Toyota and its suppliers. In America there is the TSSC or Toyota Supplier Support Center which helps improve suppliers and even consults companies outside the auto industry. Obviously it is important to Toyota that the suppliers are as efficient as possible. A way to rank suppliers has been put in place and companies that have a low ranking number are helped in order to address the concerns [1].

Principle #12: Go and See for Yourself to Thoroughly Understand the Situation (Genchi Genbutsu)

The main point of Genchi Genbutsu is simply to go and see situations for ones self. Unless items are observed firsthand it is difficult to get a clear idea by relying on details put together in a report. When a particular issue is being analyzed one may resort to using common sense and assume what the results are. At that point common sense may lead to guessing, some circumstances could have been over looked. By collecting data first hand one can tell if the assumptions were correct.

There were many examples of going and seeing for ones self discussed in The Toyota Way [1]. One strange example included a case where the boss had someone stand inside of a circle for 8 hours to observe a process. This would get boring very quick, but if you actually stay focused and observe the process in detail you may be able to evaluate it and think of alternative ways of doing things. This situation would not likely work within the U.S. very well as it Is a fairly unusual request to make. Another example of commitment to this principle deals with a Toyota employee driving through all 50 states, Canada, and Mexico in a Toyota Sienna. They wanted to see how various conditions would affect the company's targets for the U.S. market. Another example involved a manager who had moved his office from the nice business environment to a location that over looks production. This is dedication to the idea of being shop floor oriented. A simple, but inspiring example is that of the president of Toyota who reached into an oil pan to investigate an issue and prove that you should nOt be afraid to get your hands dirty.

Personnel at Toyota believe very strongly with the concept of going to see situations first hand. An example came up involving a U.S. parts supplier making a visit to apologize for an issue that had come up. The supplier representative assured everybody that he would see to it that everything would be resolved. At the same time he said that he was unsure of the cause and corrective action as he does not normally deal with such details. The Toyota personnel were shocked that someone of his ranking would arrive without being prepared to discuss the situation without observing the issue first hand.

It is often difficult for senior staff members to be at various locations at once to go and see it all. Technology these days makes communication much more effective. With the use of email and teleconferencing, messages can be transmitted to many people over great distances. Digital photos and videos can be sent electronically as well to help better understand situations.

Principle #13: Making Decisions Slowly by Consensus, Thoroughly Considering All Options: Implement Rapidly

Toyota is very thorough with the decisions that are made within and outside of the company. The basic idea of making cautious decisions starts with the mentality that you should never assume anything. Rather, one should verify everything with factual information. An example from The Toyota Way [1] involved a new employee working through a problem. This new employee presented their findings to the mentor whom questioned what other alternatives were considered and how did this proposed solution compare to them. The author of this paper experienced a similar situation when trouble shooting issues with an electro polishing problem. The cathodes were turning very black and sludgy, thus creating production downtime. It was a high priority issue so rapid brainstorming occurred in order to quickly settle on a solution. The author's boss then gave some other suggestions that were overlooked while jumping to conclusions. This goes to show that one should practice great patience and look at the big picture to gather data before a solution is generated. Similarly, during process validation testing, one must make sure that the correct attributes are tested to truly capture the effects of the process. If something is done incorrectly it may throw off the results and prevent the validation from moving forward, or it may pass something that is not acceptable.

Toyota personnel strive for consensus when working out decisions. This is different from many organizations where the various departments butt heads on topics and struggle to come to an agreement due to big company bureaucracy. Toyota never forgets the big picture that everyone is on the same team and they should all win. Toyota took this mentality outside of the factory walls into their community in Arizona. As a new development threatened the water supply, Toyota led a mission to get everybody to work together to come up with a solution to prevent this. With the teamwork of the community, all parties were happy in the end. Although obtaining a consensus can be a good philosophy, an extreme example practiced at Toyota is the number of signatures required for certain approvals, sometimes over one hundred.

Be sure to notify all people affected by changes before implementing something new. If something gets to the point of approval and a specific individual was left out of the decision making process, they are likely to challenge your recommendations. The author of this paper experienced this when pressured to qualify and implement a new electro polishing process. Various departments were consulted when creating the PFMECA (process failure mode effects and criticality analysis) document. When it was completed and routing for approvals, a member of the regulatory department was upset because they were not involved with the decision making process. The quick solution to address this was to pull everyone together at the last minute to discuss what recommendations should be added and there were few.

Principle #14: Become a Learning Organization Through Relentless Reflection (Hansei) and Continuous Improvement (Kaizen)

Toyota takes great pride in the fact that they have become a learning organization over the past few decades. To create a culture that accepts this mentality is a huge battle to conquer. As it was stated in The Toyota Way [1], many organizations have problems reaching that point as they quickly look for improvements in the bottom line and often implement quick fixes. Often there is too much firefighting and inferior fixes implemented which may not resolve the true root cause.

True problem solving involves identifying the root cause of the problem. This can be done by using the 5 why methodology discussed in Chapter 3. Keep asking why until going beyond the basic source of the issue to the ultimate root cause of the problem. It is at these deepest levels of causes that you want to implement countermeasures. This will prevent any of the other next level causes from even occurring. Once the situation is optimized, this should then be the new standardized process, until further improvements of course. Before fully pursuing the 5 why practices, one must make sure they truly have a grasp on the situation so that they go in the correct direction when looking for the root cause.

At Toyota a common practice for young engineers is to present what they have learned to the president. The president will then give feedback to the individual regarding the situation. It may involve comments that can be taken as criticism, yet it is intended to teach a lesson. Americans are not accustomed to receiving constructive criticism. This often brings about a feeling of negativity and may result in blaming something or someone else. At Toyota this is taken as an opportunity to improve so that next time this newly acquired knowledge will be useful.

Japanese culture supports the idea of Hansei which roughly means reflecting although its true translation is much deeper. This belief goes hand-in-hand with kaizen. For example, at Toyota if something goes wrong, the person in charge will be saddened and feel the need to create a solution. It will not be a quick solution; it will be a well thought answer that the person will sincerely believe will prevent the problem from reoccurring.

When employees are expected to learn and perform to a certain level, expectations need to be well laid out. If there are goals to be met, they should be specific, measurable, and challenging. These goals should be posted publicly and updates should be shared regularly. This increased awareness will help motivate people and interest them as reaching the goal will feel like a game. Obtaining results is very much a psychological event. In order to get the buy-in of employees they must have a desire to improve. They will then be open to learning new things and implementing new ideas.

Chapter 5

KAIZEN EXECUTION

KAIZEN IN ACTION

This chapter discusses a few examples of kaizen events which the author of this paper was involved with. Details will be described such as the structure of the kaizen week and what improvements were implemented. These changes are not applicable to all environments, but they show how a team addressed the problems at hand.

These examples involve a medical device manufacturer which is the employer of the author. This company is a fairly young medical device manufacturer located primarily in Minnesota which has been built up through various mergers of smaller companies. They focus on the endovascular market such as stents and delivery systems (catheters). However, other products such as embolic protection, liquid embolics, balloon angioplasty, guidewires, snares and thrombus management systems are also manufactured.

Due to the rapid growth this company is experiencing, lean manufacturing and continuous improvements are huge topics of discussion. The author's company has a designated area where kaizen and all lean activities operate out of. Kaizen events are very common; however the structure for conducting them has changed over the past 2 years.

The kaizen events consist of cross functional teams typically including engineers, supervisors, managers, production operators and administrative functions such as finance or marketing. It is common to utilize people unfamiliar with the targeted area to allow opportunity for questions from fresh eyes and prevent people from being bias. Team leaders selected by management attend intense training on lean manufacturing and kaizen practices. These team leaders are then assigned areas to improve and a date that the kaizen event will take place. The team leaders work with each other to determine who the team members should be for the various events. The team members are given notice that they will be supporting a kaizen event and that their time be solely committed to it for the entire week. Depending on the type of improvement activity, the team may get together before the kaizen event to discuss what data needs to be collected. If it is a 5S activity this is usually not necessary, although if it is a 5P event such as the first example discussed in this chapter, data had to be gathered beforehand.

5P in Action

The example discussed here involves a kaizen event that the author participated in during April of 2006. This was a 5P event which followed the "5 Principles for Problem Solving" techniques in the stainless steel stent fabrication. Along with the author, the team consisted of seven other individuals. It was a cross functional team which included the value stream manager, engineering supervisor, lean manager, an engineer, production supervisor, production lead, and two operators. The kaizen event began with the team coming together 2 weeks before the actual event took place in order to determine what data should be brought to the formal event. Scrap data was analyzed to see which scrap codes were the big hitters to focus efforts on. Two of the major reject causes were "mechanical damage" and "over micro blast" of the stents. Another large reason for scrap at the time was "laser FM," which was somewhat still questionable as to what the cause was. The author had already begun experiments to prevent laser FM scrap so this was decided to be set aside. A quick value stream map was then drawn out to get a clear visual understanding of how product routed throughout the operations and where scrap was likely occurring. Action items were then assigned to the team members, which can be seen in Appendices #1 and #2. This included collecting scrap data per code/shift/operator, scrap samples and correlating photos.

Two weeks later, the group reconvened on a Monday and dedicated an entire week to this 5P event. The team started by filling out the 5 Principle for Problem Solving forms which can be seen in Appendices C and D. The first problem to be executed was regarding mechanical damage of the stents. Step #1 involved identifying the problem statement and problem definitions. It was specified that mechanical damage was, "Any cell geometry that has been mechanically (physically) altered out of normal range, structure or drawing (see Figure 1 and Figure 2), i.e., not bends, kinks, stretch, crushed, deformed, broken." For the problem definition "What" was that this defect occurred more often on the longer stents. The "Who" that would catch this defect were the inspectors and operators at the assembly level operation. The "Where" was on the entire stent however mechanical damage is more often found on the ends of the stents and can happen at every operation. The "When" involved new operators, at every operation although operations 40, 90, 100 and 120 were the most common. The "How much" was expressed as 472 scrap pieces, or $28,174 worth of product up to that point in the year, which was 3½ months.

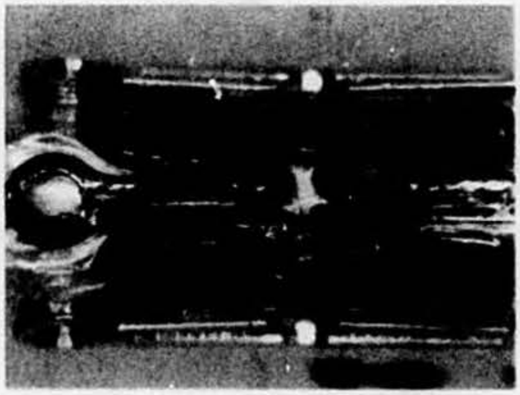

Figure 1

Mechanical Damage #1

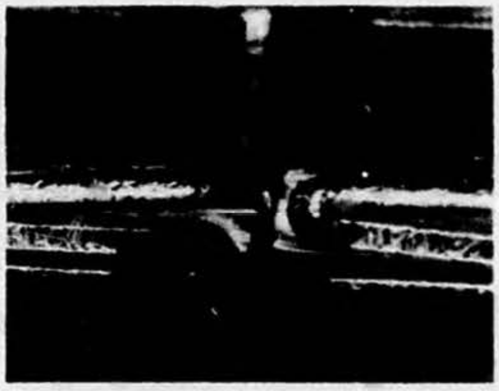

Figure 2

Mechanical Damage #2

Step #1 went further into problem identification and basically used the fishbone diagram methodology to help facilitate brainstorming. First is Machine, this is a very operator dependent operation where loading stents onto mandrels and blasting with a wand is very tedious. Second is Material, this could involve micro blast tubing having too large an outer diameter therefore the stents fit tightly onto it. Third involves Man, which uses the "touchy feely" skill of handling these delicate products. People can easily drop the parts if not being careful. Next is Method, which could include the stents hanging off of the mandrels allowing them to be damaged (see Figure 3 and Figure 4). There are no visual criteria for allowable bends; tweezers were used to pick up multiple stents at a time (see Figure 5). Brushes were used to clean the stents ID's and test tubes had rounded bottoms which did not allow for a nice surface to rest on and stents were set into small trays while measuring the masses. All in all there was a lot of opportunity for mechanical damage to take place.

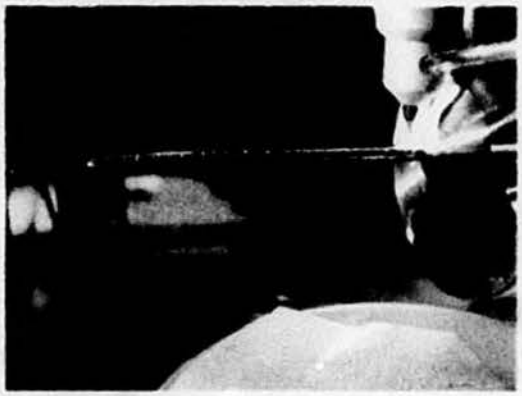

Figure 3

Part Extended beyond Mandrel

Figure 4

Hand Damaging Part Extended beyond Mandrel

Figure 5

Picking Up Multiple Parts

Step #2 involved digging into the root cause of mechanical damage. One broad scope cause is the obvious result of over handling of these delicate stainless steel stents. A common example of this was the method used for cleaning the stents at that time. It consisted of three separate cleaning cycles in three different solutions, each for 15 minutes. This meant that the stents had to be dropped into and dumped out of beakers three times. The practice was supposed to involve putting the solution into the beaker first to avoid damage of the stents hitting the bottom of the beaker. However, it was possible for liquid to be poured onto the stents and they could get swooshed around in the beaker (see Figure 6 and Figure 7). Tweezers with cupped ends were then used to pick the stents out of the beakers if they did not fall out on their own. Naturally, if a person was not cautious they could have smashed the stents. Mechanical damage was likely to occur during the loading of mandrels at electro polishing, riveting and micro blasting. The most vigorous was that used at electro polishing. The stents fit very tightly onto the mandrels so it required a special touch to avoid crushing the stents or flaring the ends open.

Figure 6

Pouring Liquids onto Parts

Figure 7

Swooshing Parts in Liquids

Step #3 covered the corrective counter measures for the issues mentioned. One option was to use baskets for transporting the stents from beaker to beaker during the cleaning process. Plastic baskets were purchased, however, they were too large and plastic absorbs ultrasonic frequencies too much. Prototypes were then made out of stainless steel, however, there was a concern that the metal baskets would react with the chemicals and slow the cleaning process (see Figure 8). The basket idea was thrown aside and the author developed a new cleaning process at a later date that removed two of the three 15-minute cycles so time was reduced in addition to handling. This also allowed for a more effective cleaning process so the stent ID's no longer needed to be brushed, thus preventing the laser FM scrap problem.

Figure 8

Basket Prototype

Another item that was addressed was the opportunity for operators to use compressed air for drying stents. It was known that some people had used the air hose if they were in a hurry and did not want to wait for the fans to dry the stents (see Figure 9). This was obviously bad practice as the operator would risk squeezing the stent to prevent it from blowing out of their hand. Contaminates in the air lines was another concern although the stents were cleaned a few times further downstream. It was not necessary to have the compressed air hose near the inspection areas so it was removed and the use of the driers was enforced (see Figure 10). The use of the metal tweezers was desired to be omitted, but they were more effective than the plastic ones. In the end, the metal tweezers remained in process; however they were only to be used to pick up one stent at a time.

Figure 9

Drying with Compressed Air

Figure 10

Proper Fan Drying

The team spent much of the week out on the production floor watching the operators perform various operations to get a better understanding of what the stents were experiencing. It was found that more mechanical damage was occurring than was getting recorded as scrap. Some minor bends were getting reworked although it was not known how much. A simple data collection sheet was then implemented short term to monitor the rework and scrap for mechanical damage after riveting and micro blasting. See Appendix E for the form. The team needed to know how much effort was being put into reworking the stents to fix the bends. It turned out that the many of the stents were getting reworked to some degree, although mostly for very minor, unnecessary mechanical damage.

Beyond isolating causes for mechanical damage and implementing improvements, the author wanted to determine how different severities affected product performance. A simple study was done which looked at different degrees of bends before and after crimping the stents onto balloons. The results showed that the overall stent lengths were still within specification and they still expanded adequately. No changes were made to the visual standards reflecting this due to the risk of accepting lower quality stents without formal testing.

The other scrap code that was investigated was the defect known as over blast. This is associated to multiple visual characteristics although they are all caused at the micro blasting operation. The problem statement described this as micro blasted surfaces that extend past the specification in the inner diameter of the stent and also any micro blasting done to the outer diameter; see Figure 11 for OD blasting.

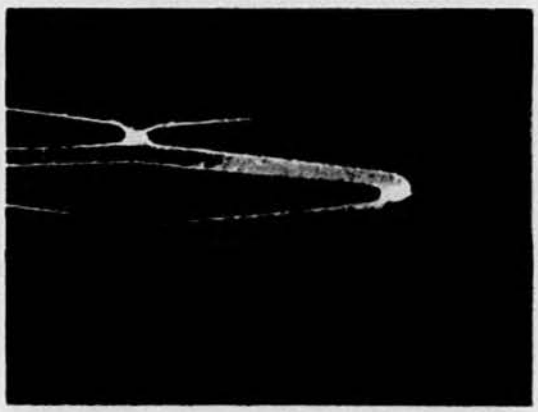

Figure 11

Over-blast on OD

During the problem definition the "What" was all stainless steel stents that get micro blasted. It could be observed as strut thinning as the blasting could have been done too much in a concentrated area, see Figure 12. The "Who" could involve everybody from the inspector to the patients. The "Where" pertained to the ends of the stents on both the inner and outer diameters. "When" was at the micro blasting operation (Op 100) and reject rates were found to be higher during second shift. This being a very operator dependent process showed that training may not have been up to par for the second shift operator as they had higher scrap rates. It was also proposed that over blast may be more problematic as the nozzles wore. If the nozzle inner diameter wears and gets larger, the spray of the abrasive material fans out. This makes it difficult to control the media, thus blasting the outer diameter of the stent. The "How much" was expressed as 547 pieces, or $33,577 up to that point in the year, 3½ months.

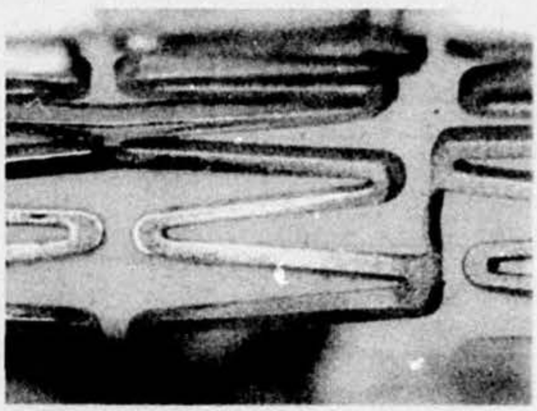

Figure 12

Over-blast on ID

The fishbone diagram for brainstorming the over blast problem definition included some useful details. The Machine items included the chuck being wobbly, nozzle inner diameter wear, clogged nozzles causing irregular flow, lack of replacing fixtures regularly and the possibility of the equipment orifice wearing out. The

Material contributors involved the nylon tubing outer diameter potentially being too small, thus the stent being loose on it. Stents being bent prior to micro blasting could cause a problem if they wobbled when the motor turned on or the stents did not fully contact the masking mandrel. The Man related issues were unsteady hands, lack of attention, and the use of the wrong fixture. This being a very operator dependent operation meant any of these were very likely. Causes stemming from the Method were the obvious improper technique of inserting and holding the nozzle correctly while the stent is spinning. This was a very poor design relying on operator technique. The dimensional specification has always been very tight so this was not helping the problem. Other contributors to the over blasting problem could have been inadequate lighting and low visibility due to lack of magnification.

In general the micro blasting method is not reliable because of the operator dependency. The author had a few different versions of an automated micro blasting work center quoted, but they came back very expensive. The company is now working on its own design that could be built in-house. It was also investigated to remove the micro blasting operation all together, but the testing was somewhat inconclusive for justifying that the roughed up area does much for the stent retention on the balloon. To be conservative, it was decided not get rid of that operation. One small improvement that was done involved the replacement of the motor which rotates the stent, as it was concluded that the old one was getting worn and sloppy. Action items were tracked for given goal dates per the Kaizen Newspaper found in Appendix F.

It can be observed that this 5P event was rather successful in addressing some root causes to a few major scrap problems. The yields improved immediately and have been maintained quite well. Not only was it a success, but this kaizen event was a great learning experience for the entire team. It was an enjoyable activity where everyone learned many things; product quality was improved allowing the company to save money.

5S in Action

The next kaizen event discussed involves a 5S activity which the author of this paper was a co-leader for. There were four 5S events being executed in parallel for various product lines during the same time period. At the end of the predetermined time frame each area was judged and awards were distributed. The teams were selected in a similar fashion as the 5P kaizen even listed previously, although it was not the norm, all of the team members belonged to the affected areas.

Regarding the author's team, the week started out with 5S training on a Friday due to a holiday during the following week. The training began at 8:00am with a 15 minute overview of what the following week would involve and the areas covered. Next, the seven wastes were discussed in detail similar to Chapter 4 of this paper, followed by the 5S principles similar to Chapter 3. Visual controls were then covered, followed by mistake proofing. After a short break the group went over set-up reduction concepts and then much time was spent on standardization. This went up to about 10:45 when the team leader went over the charter specific to the group's focus.

Everyone then went out to the production floor to tour the areas and discuss wasteful practices. From that point out the team executed 5S methodologies throughout the predetermined areas. The team leaders and co-leaders touched base at the end of each day for status updates. At this company, the kaizen week typically ends with a report out to management; however this was not the case for these events. The teams were given additional time to execute longer term improvements generated during the original week to allow for items to be purchased and fabricated.

On Friday afternoon, the author's team began executing 5S methodologies at the operations most familiar with them, riveting, cleaning, and compaction of medical devices. The next areas to be addressed the following week were the fabrication lines and laser cutting areas. The fabrication lead, laser cutting lead, laser engineer, stainless steel device engineer, and operators all assisted with the simplifying steps. Simplifying was the most labor some task as it involved taping off and labeling all of the work stations, tooling and equipment. The below discussions illustrate the before and after photos in the order that the operations occur to keep the processes in sequence.

Figure 13 shows the rack that product sits on before it routes through post laser processing. Originally there was no method for determining which lot of product to take next. Figure 14 shows the post-5S event photo including new product labels and FIFO (first in, first out) labels indicating which lot of parts to process next.

Figure 13

Old Product Staging Rack

Figure 14

Product Staging Rack with Labeling

An example of reducing time and motion waste can be observed in Figure 16. Notice the additional tooling located on the shelf which is not present in Figure 15. Historically this tooling was acquired by the operator by walking to another room to get it from a single location several times a day during changeovers. After the 5S event the tooling was placed at the point of use so it can be observed if anything was missing.

Figure 15

Expansion Operation before 5S

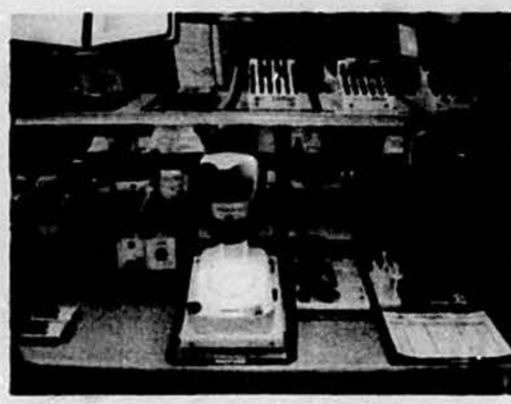

Figure 16

Expansion after 5S

Figure 17 shows an operation which was fairly unorganized. The benefit to simplifying is that it allows someone to tell at a quick glance if something is missing. It can be observed by the after photo in Figure 18 that all of the items have a home.

Figure 17

Weighing Station before 5S

Figure 18

Weighing Station after 5S

An example of visual aids can be found in Figure 20 which shows a small green sign in the upper portion of the photo. This is an equipment status sign that was implemented here and at three other operations. It was added in order to give direction to technicians who come to work on the equipment. If a machine is down, the sign is flipped over to show that it is not operational. When many pieces of similar equipment are on the floor, this makes it easy for the technicians to locate the ones that are problematic.

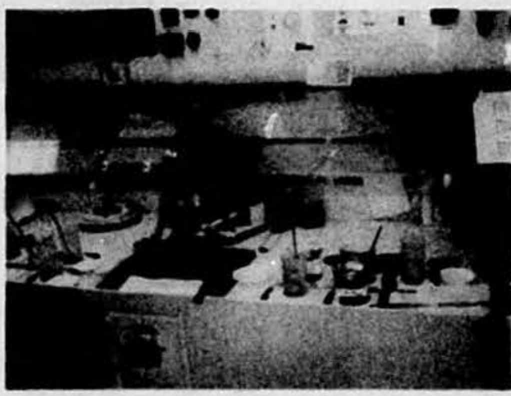

Figure 19

EP Station before 5S

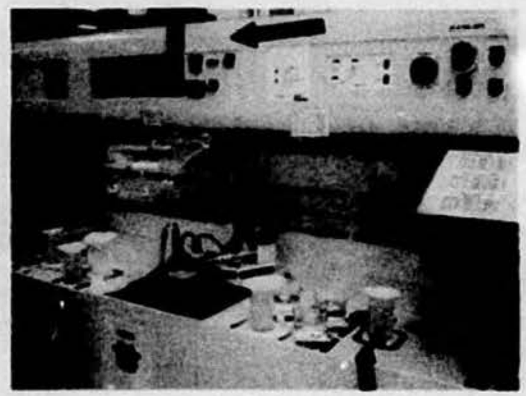

Figure 20

EP Station after 5S

Through the 5S methodologies of sort, the red bins and gray rack in Figure 21 were removed from the start of a product line as they were not necessary. This also followed the rule of standardization as the color red is the standard color which means scrap when in reality they were used to store good product. The use of shelves in Figure 22 served the purpose well especially with the addition of FIFO labels to control product sequence.

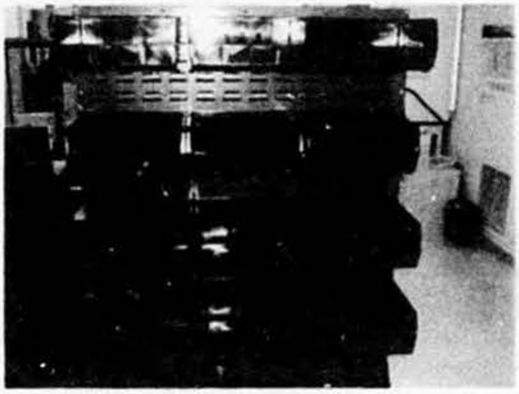

Figure 21

Riveting Staging Rack before 5S

Figure 22

Riveting Staging Rack after 5S

Some basic 5S principles already existed in Figure 23 such as the simplifying seen with the taping off and labeling of items. However, notice in Figure 24 the red bin was removed and plugs were added to the tooling holder. The plugs covered unused holes so that only one hole is vacant when a piece of tooling is being used. This way it is obvious if one was missing.

Figure 23

Riveting Prep Station before 5S

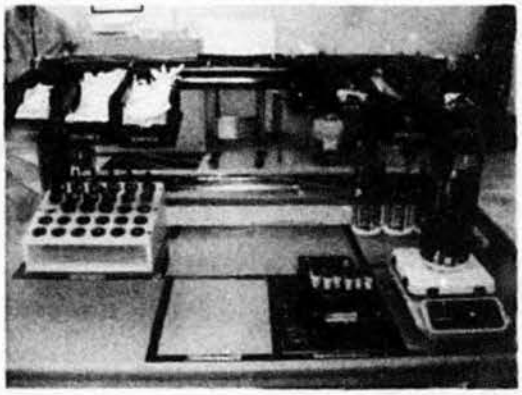

Figure 24

Riveting Prep Station after 5S

The process shown in Figure 25 was confusing as the use of a color coded flow chart was created inline while the flow of product through beakers was not. Figure 26 shows the simplified layout of the timers and colored flow sheets to correspond with the beaker layout below them. Additional timers were also implemented so that operations would not need to share them. This greatly reduces the opportunity for errors.

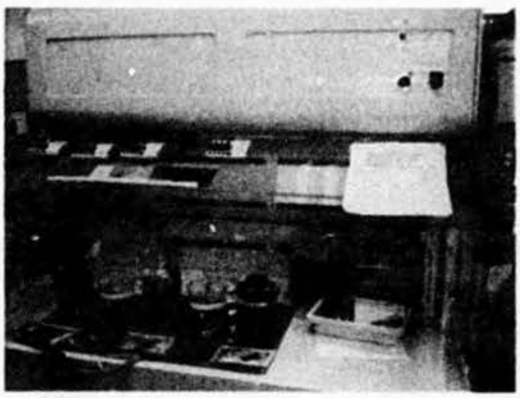

Figure 25

Cleaning Station before 5S

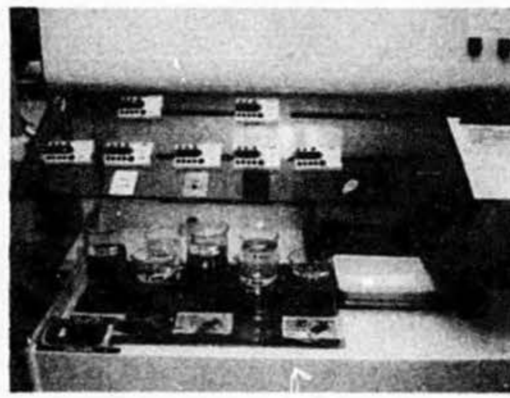

Figure 26

Cleaning Station after 5S

Historically, DI waste water was removed from the main jug through a drain hose into a shuttle jug by gravity. This was time consuming and a back pain for the operator. The 5S team simplified this by adding a pump seen in Figure 28 which omitted the need of a shuttle jug. The emptying step could now be done very quickly by pumping the water directly into a sink.

Figure 27

DI Water Cart before 5S

Figure 28

DI Water Cart after 5S

Figure 29 shows a very large wire rack that was used for the NCMR or nonconforming material report area. This shelf was underutilized, so basically a waste of space. The 5S team decided to replace this rack with the one in Figure 30 which is much smaller. In addition to that, the shelves were labeled per product line to keep product segregated.

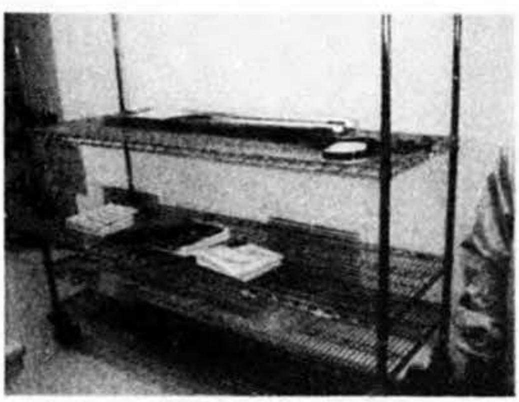

Figure 29

NCMR Rack before 5S

Figure 30

NCMR Rack after 5S

In general Figure 31 shows how the storage bins appeared at many of the operations before the 5S kaizen event took place. There were often random items present, likely not even necessary at that operation. After the 5S event the bins were labeled similar to those in Figure 32 so that each item had a specific home. If the item was not called out on the label, it shouldn't be in the bin.

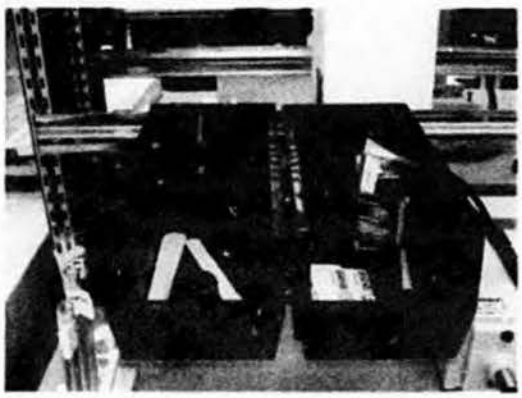

Figure 31

Storage Bins before 5S

Figure 32

Storage Bins after 5S

During 5S events, all of the items that are determined not to be necessary are removed from the areas. These items are then red tagged and placed in a special location where they can be claimed by other departments that can find a necessary use for them. If the items are not useful to anybody they should be discarded rather than take up space in storage. Figure 33 shows the items removed from an area during this 5S event. Many of the items were always present with no known use.

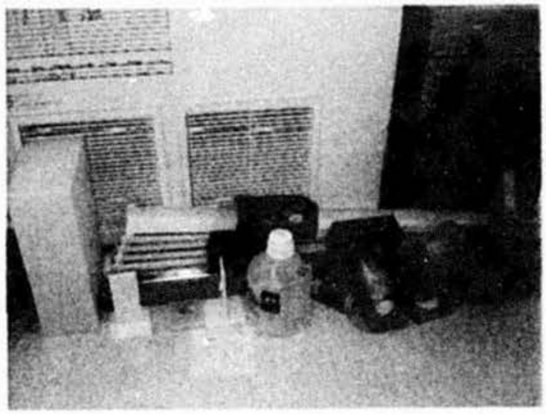

Figure 33

Red Tag Items

Chapter 6

KAIZEN IN THE OFFICE ENVIRONMENT

Over the years many industries have experienced rapid advancements in technology. This has lead to higher quality products and reduced costs. Lean manufacturing principles are continuously being practiced on the production floor to support improvement initiatives. However, a sector of the business that is often overlooked is that of the office environment. This is unfortunate because so many activities take place in the office that manufacturing depends on. This is why companies need to shift gears and focus attention to office kaizen to minimize wastes which ultimately slow down the entire business. "Office Kaizen is an implementation path, management philosophy, leadership structure, and set of tools, all wrapped into one consistent package" [3].

SURFACE WASTES WITHIN THE OFFICE

Lean practices in the office strive to minimize much of the administrative wastes which are present; various types of these wastes are discussed below.

Processing Waste

When people do not perform as well as they could be, it is considered processing waste. The people may be working hard, but that may be exactly the problem, they are working hard when they should be working smart. This is often the cause of poor training which can be addressed by using formalized procedures to ensure employees perform tasks properly.

Waiting Waste

A very common example of waste that occurs in the office is in the form of waiting. Examples could be the time spent waiting on hold during a phone call. The time taken to acquire additional signatures on documents requiring approval is wasteful. Sitting in a conference room waiting for late attendees to show up is a waste of everyone's time not to mention if the meeting is not productive [7]. Each of these are common events that are often overlooked. It is usually not until all of these are minimized until people realize how inefficient they really are.

Scheduling Wastes

Scheduling waste directly impacts the production floor through the resources required to compensate for a poorly scheduled production plan. If certain constraints are not considered and scheduling is done in a fashion that has unrealistic or inefficient expectations, the production support personal need to perform additional tasks to make things work out. This may involve scheduling jobs in presses located on opposite sides of the building from each other when they normally run adjacent to one another to marry the components together. A material handler would then need to facilitate movement of the parts to get assembled. Scheduling waste can also be minimized with proper procedures and thorough communication between production support and scheduling departments.

Work-Around Waste

When processes are not followed and extra efforts are exerted to work around the system, it is considered work-around waste. This can be tempting in highly regulated industries such as the medical industry where there are set requirements and procedures for facilitating business practices. Often, the formal methods are very time consuming, but it is important that they are followed to prevent future issues. If people work around the system and face problems down the road, additional resources, thus waste, will be required to address the initial problem.

STRUCTURE OF CHANGE

Most people will agree that there are many forms of waste in every aspect of business. The practices of Office Kaizen discuss some methodologies and structure for addressing such inefficiencies [3].

SLIM-IT

SLIM-IT is an approach for aggressively attacking leadership wastes that hinder an organization and it promotes continuous improvement. SLIM-IT is how the acronym SLMMTTTT is pronounced, which stands for structure, lean daily management system (LDMS), mentoring, metrics, tools, teamwork, training and technology. These are all mechanisms that teams should focus on to empower office kaizen.

Executive Steering Committee (ESC)

The top of the structure consists of the executive steering committee which is the top level management committee involved with office kaizen. "The role of the ESC is to guide, prioritize, direct, focus, coach, counsel, and make decisions on critical change parameters" [3]. They charter a cross-functional change team to determine solutions and then they meet weekly to review progress of projects.

Change Teams

Change teams consist of a cross functional group determined by the ESC. Their purpose is to drive a significant change initiative, typically kaizen events, in order to improve a problematic area, process or situation.

Champions

Each of the ESC members is assigned to be a champion of a change team. They should not work with a team involving an area of their direct responsibility. Therefore, their purpose is to act as the coaches rather than assist in generating solutions. The champion works with the ESC to recruit a team leader for the given change team. They help the team leader select the team members and assist them in fine tuning the charter. The charter is a basic document to provide direction for the team. It typically consists of a mission, objectives, names, activities, responsibilities, deliverables, schedule and critical success factors.

LDMS

The LDMS or lean daily management system is a methodology that provides structure, discipline and ownership to each of the intact work groups. The LDMS is simply normal business practice that occurs in everyday work. Intact work groups, or people who work closely together on similar processes follow LDMS and its elements to be effective. These include meeting daily for status updates, the use of visual displays for communication, the use of action sheets for kaizen events, contact with leaders for reviewing recent items and assessment of long term improvement plans. Following each of those is important for a team to function well

Improvement Approaches

First of all, in order for meaningful improvements to be implemented, the true problems need to be identified. A scorecard can be used to monitor specific metrics in order for people to look at a glance and see where issues may be present. When it is determined that something needs to be looked into, a nice analysis tool to use is VSM, or value stream mapping. This can have a broad or narrowed scope depending on the situation. VSM allows an area to be dissected in order to trace the flow of materials, then locate and eliminate non value added work [12]. Unfortunately VSM will not fix the problems; it just helps to see where attention should be focused.

Once the problematic areas have surfaced, the team must brainstorm solutions in order to address the problems at hand. This typically results in reengineering of a process or design or implementation of a lean manufacturing methodology.

A common solution to problems or inefficiencies in the office area involves the use of enterprise software. With advances in technology, many companies have software packages that work with most of the business systems. It would ideally manage all of the documentation necessary for the company to operate in addition to communicating data for areas such as finance and operations. Examples could be the standardized procedures, historical test results, paperwork for work orders, electronic CAD files or even HR related items like vacation time availability and training programs.

Chapter 7

CONCLUSION: BRINGING IT ALL TOGETHER

DEVELOP A LEAN CULTURE TO SUCCEED

For a kaizen event to be successful, it is crucial for the company culture to be aligned with the lean principles. If top management does not buy into and promote the lean ways of thinking, neither will other levels of the organization [14].

PREPARE CAREFULLY AND HAVE CLEAR OBJECTIVES

As mentioned in previous chapters, it is important for the team to have structure such as an experienced team leader, a developing co-leader, and a mix of employees from the affected area along with members from unrelated areas. This allows for insight into historical problems in addition to fresh sets of eyes to raise new questions.

Data behind existing issues (if present) should be gathered so that the team does not have to waste their time looking for such information during their already intense week. Examples could be scrap quantities and at what operations, or downtime hours for equipment. Depending on the purpose of the kaizen event, different information is needed. Another item that may be useful is to draft a detailed value stream map for a visual aid of how product routes through a specific department [19]. This will show what steps are useful and what steps can be removed.

When the team gathers, it is important that everybody understands the basic lean training such as the seven wastes and why they need to be minimized. Also, the team members should be aware of the different kaizen tools available so that they are aware of the benefits. For example, the purpose of SMED is to minimize set up times to reduce downtime and increase throughput. If employees at every level do not understand these simple methodologies, they may not truly respect the efforts that are being focused during the kaizen event. It is also extremely important to get input from the employees that work in the affected areas. If they have voiced their opinions in resolving problems, they will be much more accepting of the changes that get decided upon. Resistance at the shop floor can be a very destructive situation. One must be careful not to hinder moral by swooping in and changing the ways people work without good reason.

Beyond the structural and intellectual preparations, one should also remember to have physical supplies ready for the kaizen event. Depending on the event scope there are many things that could be necessary. Several examples being: Colored vinyl tape, label maker, razor blades, digital camera, stop watches, clip boards, video camera, projector, tape measure, sticky notes and of course a conference room for regrouping [2].

MAINTAIN FOCUS THROUGHOUT THE WEEK

It is very important for the team to stay on task with the predetermined objectives. It is likely that various issues will surface during each kaizen event so these items should be documented and discussed at the end of the event as long term improvements. These issues can then be addressed by the appropriate people based on the priorities at that time. With respect to focus, it is important for each team member to keep the kaizen event the number one priority during the designated week. Other work should be scheduled accordingly to free up this time. For example, production should ramp up for some time period before the kaizen week as there will likely be much down time. Although at the end of the kaizen week, production should start back up and run to new standards or processes if they were changed to ensure that no new problems exist. Small details like team t-shirts are sometimes worn for motivation and serve as a reminder that the particular person is designated to a specific cause for that time period. It is also common for lunches to be provided for team members. This allows for a break with all of the team members in one location to share updates.

SUSTAINING

One of the most challenging aspects of kaizen events is sustaining all that has been accomplished. Someone can be extremely talented in implementing the kaizen tools such as 5S, SMED, etc., but if they do not put a system in place for sustaining the improved state, everything will likely drift back to the original inefficient ways over time [20]. This is where auditing comes into play. Using forms such as those found in Appendix G and H on a regular basis will help motivate employees to continue the lean practices and improve over time. These forms are for recording scores for each area so they can be monitored over the long term.

As stated earlier, the big picture for kaizen events and lean practices is to remove waste. No matter what task or industry is involved, professional or personal, everybody should strive to continually improve themselves and their surroundings.

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REFERENCES

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APPENDICES

APPENDIX A

Action Items from "Five Principles for Problem Solving" SS Fab. Project

Action Items From "Five Principles For Problem Solving" SS Fab. Project

Data Needed To Better Understand Mechanical Damage Scrap

Action items	Owner	Status
Collect scrap data specific to part number so it can be determined if length and tubing OD affect the issue.	Bob B. (Mike E.)	Continuing
Determine if certain areas of the stent are more likely to be damaged.	Dave B.	Not likely, EP consistent
Photos of defects.	Dave B.	Complete 19-APR-06
Collect scrap data on a daily basis (short term)	Bob B. (Mike E.)	Continuing
Compare the scrap data from before, during and after 2nd shift existed.	Teresa B. & Jim P.	Specify 1st or 2nd shift
Collect data after riveting and microblasting operations including # started with, # scraped for mechanical damage, # reworked for mechanical damage and # completed.	Teresa B. & Jim P.	continuing
Look up the 2005 scrap totals for this issue. (%'s)	Bob B. (Mike E.)	

~ Based off of discussions from meeting on 12-APR-06.

APPENDIX B

Action Items From "Five Principles for Problem Solving" SS Fab. Project

<u>Action Items From "Five Principles For Problem Solving" SS Fab. Project</u>

Data Needed To Better Understand Over Micro Blasting Scrap

Action items	Owner	Status
Collect samples of scrap.	Dave B.	Complete, still collecting
Collect scrap data specific to part number so it can be determined if length and tubing OD affect the issue.	Bob B. (Mike E.)	
Photos of defects (excessive ID, and presense on OD)	Dave B.	OD complete 19-APR-06
Collect scrap data on a daily basis (short term)	Bob B. (Mike E.)	Continuing
Has there ever been a customer complaint	VOID	
Check micro blasting MP to see if it specifies mass removal (ex: 1/2 the strut thickness...)	John R.	Complete, does not specify requirments. Print has length spec.
Could strut thinning be caused upstream?	Dave B.	Measured polished stents and the i-struts were consistant
Compare the scrap data from before, during and after 2nd shift existed.	Teresa B. & Jim P.	Add a column to show shifts
Put together information showing the relationship of specific operators to scrap quantities.	Teresa B. & Jim P.	Complete, still collecting
Look up the 2005 scrap totals for this issue. (%'s)	Bob B. (Mike E.)	

~ Based off of discussions from meeting on 12-APR-06.

APPENDIX C

Five Principles for Problem Solving

5 PRINCIPLES FOR PROBLEM SOLVING

Team: John Randby, James Khan, Teresa Bergquist, Dave Buye, Bob Brown, Jim Powell, Sue Bengtson

Date: 24-Apr-06

Step 1 PROBLEM STATEMENT

Any cell geometry that has been mechanically (physically) altered out of normal range, structure or drawing. Ie not bends, kinks, stretch, crushed, deformed, cracked, broken.

Measured at Scrap Cdc. IT Otto - Mechanical Damage

Use the 5W and 2H to provide as much factual information about the problem as possible

1 - A PROBLEM DEFINITION (Problem Side)

	IS	IS Not
What	occurs more on longer stents 1. Bent 2. Kinked 3. Deformed	Cracked or broken Measured
Who	Downstream Operators Op 90 reworked 77/275 Top Assembly Op 90 reworked 77/275 scrap 0 Op 100 reworked 85/309 scrap 3	
Where	Can be on entire stent - most often on ends Inspected at OP's 40, 90, 100, 120 Potentially occurs at every operation	inspected at other OP's
When	OP's 40,90,100,120 - Has always been there Occurs with new operators (50% one operator) Potentially occurs at every operation	
How Much	472 Since Jan 1, 2006. This week 35/190 18% of scra	

1 - B PROBLEM DEFINITION (Clarifying / Pinpointing Facts)

Part check results, factor analysis, quality condition of current part / process.

Question and answer analysis problem

2 - A IDENTIFY ROOT CAUSE (Question and Answer Analysis) From Fishbone Chart

PROBLEM (1)	WHY (2)	WHY (3)	WHY (4)	WHY (5)
Over Handling During (A) Cleaning MB Cleaning and Passivation	1) Need To Drain Solution 2) Need to Place Stents in a Clean Beaker	1) To use next Solution 2) Help Remove Loose FM	1) For Process 2) Continues To drain the Stents	1) [illegible] Challenge Process 2) To Further Clean Stents
No Spec Relief For Bent, Kink or deformed				
Sliding Stent onto Mandrel or Mandrel Causes damage	Nylon Tubing Used To [illegible] [illegible] [illegible] Tube [illegible]	1) Tight fit is the design so stent doesn't [illegible] on Fixture 2) Stent ID is Reduced for handling		

Content of C/M
Prediction of effects

2 - B IDENTIFY ROOT CAUSE (Summary)

occurrence process, duplication test.

Root Cause Statement / Illustration

(A)
- The draining of Solution and Removal of Stents - Using Tweezers or Fingers from Beakers or Filtered Funnels Can Cause damage. This happens a Total of 9 Times Through Process.
- Implement a basket That Can move from beaker To beaker
- This allows: 1) Reduction of Times That Stents are handled during Cleaning i.e moved from one Beaker To another 2) Pouring Solution into beaker before the Stents are placed in the beaker

(B)

(C) C/M Action Taken (A) Implement use of [illegible] (A) Eliminate Hand [illegible]

Step 3 CORRECTIVE COUNTER MEASURE(S) Prevention of failure

Identify Temporary and Permanent	Who	When
Eliminate Hand [illegible] [illegible]	Sue B.	[illegible]
Implement The use of baskets To move Stents from one beaker to another		

Step 4 CONFIRM COUNTERMEASURE(S Actual effects

	Who	When
Daily [illegible]	Teresa Bob	24-Apr-06

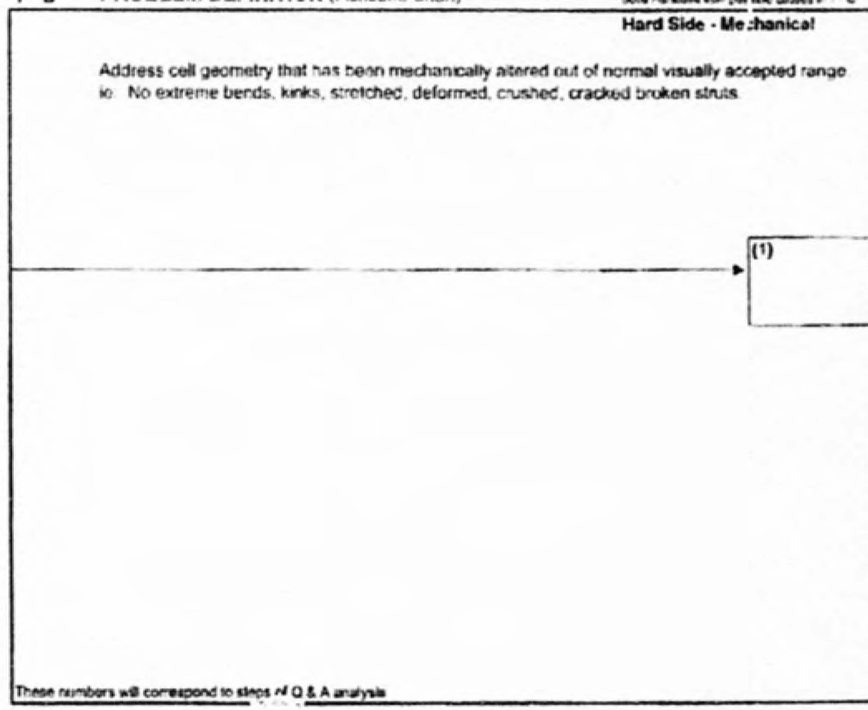
Step 5 FEEDBACK/FEEDFORWARD

	Who	When

1 - C PROBLEM DEFINITION (Brainstorming)

	Possible Causes	Clarification
Machine	Microblast very operator dependent loading/unloading mandrels	
Material	Microblast tubing too tight	Mandrels have a tight fit
	S.S. too soft or hard	
	E.P. mandrel too tight	Properly pinch mandrel while loading
	Off of laser bent already	Drop as cut, fall into basket
Man	"touchy feely"	Handling requires delicate touch
	Dry with compressed air	Use air hose rather than blower
	Drop stents on floor	
	Training	
Method	Too manual	
	Over compressing stents on mandrels	
	Stent hanging off mandrel	
	No visual criteria	
	Using tweezers to pick out of beakers	
	Load/unload EP mandrel	Properly pinch mandrel while loading
	Lack of stent rollers	Manually spinning stents during visuals
	Brushing ID	Vigorous manual operation
	Pouring liquid onto stents	Drop stents into beaker, pour liquid on them
	Radiused test tubes	Drop stents into vial, hoops bend in
	Dumping entire lots into beakers	Stents intermingle and bend
	Weighing stents (throwing into tray)	Stents tossed into scale
Etc	Temp	
	Humidity	
	Light	

1 - D PROBLEM DEFINITION (Fishbone Chart)



APPENDIX D

Five Principles for Problem Solving Sample Page

5 PRINCIPLES FOR PROBLEM SOLVING

Team: John Rendley, James Khare, Teresa Bergquist, Dave Hauge, Bob Brown, Jim Powell, Sue Bergtson

Date: 11c APR 06

Step 1 PROBLEM STATEMENT

microblast media extending past spec. ie. length of MB in ID or any overspray on OD measured as scrap code H-025. Overspray/microblast

Use the 5W and 2H to provide as much factual information about the problem as possible

1 - A PROBLEM DEFINITION IS (Problem Side) / IS NOT

	IS	IS NOT
What	SS stents - every size that is MB. (1) OD overblast visually no longer shiny (polished) (2) ID blast length out of spec.	(1) higher concentration in one area - thinning struts - width thin
Who	(1) Bottom B: Bob, Mike (2) Top assy - sera, everett (3) patient (4) MB operator (5) final inspector	(2) Low impact (3) Low occurrence
Where	(1) on ends (2) OD (3) ID (4) OP 100 (MB) / 120 (final insp)	
When	Seen @ OP 100 (1) always there (3) increased with 2nd shift (4) increased at size 2.5 (5) when nozzle is changed	
How Much	547 since Jan 1 / $33,577 since Jan 1	

1 - B PROBLEM DEFINITION (Clarifying / Pinpointing Facts)

Part check results, factor analysis, quality condition of current part / process

Question and answer analysis problem

2 - A IDENTIFY ROOT CAUSE (Question and Answer Analysis) From Fishbone Chart

PROBLEM (1)	WHY (2)	WHY (3)	WHY (4)	WHY (5)
ID on nozzle when out causing overspray on ID of stent	operator holds nozzle in same position, not compensating for size.	manual process, very little room to move	manual by design.	
(6) unsteady hands causes overblast on OD of stent (7) unprotected OD surface (8)	wrong angle causes overspray on OD of stent	no support for nozzle or hands to ensure accurate angle.	no fixture ever designed to ensure a steady hand.	
Small tolerance on ID blast spec	Started with a block tolerance of ±.005.	print never contained a tolerance.	was never challenged by designers	

2 - B IDENTIFY ROOT CAUSE (Summary)

occurrence process, duplication test

Root Cause Statement / illustration

Manual Operation

Content of C/M
Prediction of effects
Prevention of failure

Step 3 CORRECTIVE COUNTER MEASURE(S)

Identify Temporary and Permanent	Who	When

Step 4 CONFIRM COUNTERMEASURE(S Actual effects

	Who	When

Step 5 FEEDBACK/FEEDFORWARD

	Who	When

1 - C PROBLEM DEFINITION (Brainstorming)

	Possible Causes	Clarification
Machine	(1) Nobody check (2) ID on Nozzle wears out ✓ (3) clogged Nozzle (4) Fixture not replaced regularly. (5) orifice wears out	
Material	(1) Nylon Tubing too loose (2) Bent Stents (3) media grit size?	
Man	(1) unsteady hands (2) Lack of attention (3) wrong fixture used.	
Method	(1) inserting Nozzle in Stent (Holding There) (2) improper technique	
MOTHER NATURE Etc.	light (too dark?) —	could use magnification

measure / spec. too tight ✓

1 - D PROBLEM DEFINITION (Fishbone Chart)

Build Fishbone from possible causes in 1 - C

Hard Side - Mechanical

(1) microblast media extending past spec. length of MIB in ID or any overspray on OD

Soft Side - Human Factors

After completion of Fishbone Chart, number each step from big bone to small bone.
These numbers will correspond to steps of Q & A analysis

APPENDIX E

Tracking Mechanical Damage after Riveting and Micro Blasting

Tracking Mechanical Damage After Riveting and Micro Blasting

Date:
Part #
Lot #
Operator:

	Start Quantity	Reworked Tick Marks	Scrapped Mechanical Damage Tick Marks	Quantity Finished	Observations
After Operation 90 (Riveting)					
After Operation 100 (Micro Blasting)					

Note:

- 100% inspect stents for mechanical damage IT-016 after the riveting and micro blasting operations
- Place a tick mark in the appropriate column when you either rework (fix) a stent for mechanical damage such as bends or deformation or if you scrap one for the same reason if it's not repairable
- Use one sheet per lot
- If you see any trends in the defects record your observations or any other comments/advice in the Observations column
- As ussual save the scrap

APPENDIX F

Kaizen Newspaper

Kaizen Newspaper

K

Directions:

1) Fill rows with EVENT implemented items that your team completed during the week.
2) At the end of EVENT week, add items that must be completed in the next 20 days.
3) Fill in the "Plan to Close" dates (X) for the next 20 working days after the EVENT is over
4) Perform cell audit every Friday for 20 days. Indicate if items are done and working (Y)
5) Team Co-leader must update weekly the NEWSPAPER until ALL actions are completed

Total Items	8	8	8	8	8
Plan to Close	8	17	22	23	24
% Plan/week	100%	213%	275%	288%	300%
Score (Y=1pt.):	8	13	13	13	13
% Complete:	100%	163%	163%	163%	163%

Continuous Improvement EVENT Objectives: Note: 100% action completion signifies that ALL the EVENT objectives are achieved

	Item #	Problem	Action	Who?	Kaizen Week End (Date: 28-Apr-06)	5-Day (5-May-06)	10-Day (12-May-06)	15-Day (19-May-06)	20-Day (26-May-06)
MD	1	Stents are potentially damaged when moving from one beaker to the next	Make prototype of basket to place inside beakers to drain and transport stents	Bob B	y				
			Evaluate and document prototype and outline standard work for use. Visually inspect for mechanical damage and other defects. 10 stents	Teresa B, Sue B	y				
			Determine effectiveness of new strainers via fewer steps, fewer mechanical defects	Jim P, Teresa B		y			
			Effective implement through Deviation	Dave B					x
			Find PTFE Strainers at PPI	John R		x			
OMB	2	Team has multiple options for improving over microblasting automation, eliminate MB, increase spec tolerance)	Develop a pros and cons report for various options	John R	y				
			Written with signatures - a test protocol for Microblasting removal validation. Need Balloons. Need Legal clearance. 30 day Special submission	Lucas D			x		
			Evaluate feasibility of ComCo off the shelf turn-key MB system $40-70K. More parts being sent for evaluation	Dave B		x			
			Semi automated MB system. Brainstorm concepts	Dave/Lucas		x			
LFM	3	Laser FM remains after cleaning cannot be removed through current settings	Validate new more aggressive cleaning to remove dark residue remaining after EP cycle. Building samples, needs protocol signoff	David B				x	
		Realtime scrap reporting. Current reports only when lots close	Generate hour by hour detailed scrap report. Rec'd also. C4	Carla/Jim	y				
			Implement Infinity Tracking System	Teresa B, Sue B		y			

Kaizen Newspaper

K

Cost Center Department / Value Stream Department — Project Leader — Event Type

	No.	Issue	Action	Who				
MD	4	There is no spec relief for bent, kink, or deformed	Evaluate effects of bent struts on overall lengths. Measure really bent ones before straightening and see if they're still in spec	Sue B Teresa B	y			
			Look at potential acceptance of bent struts with a length check	Dave			x	
			Need Trays and pick up sticks. Get print made	Lucas D			x	
MD	5	Unknown how many times a stent is actually touched during the process	Count number of touches and define touch. Identify opportunities that cause damage 72 times	James K Sue B	y			
MOB	6	During MB the part wobbles	Change motor	Jim P	y			
			Ensure mandrels are straight	Jim P		y	x	
MOB	7	Concern that operator cannot see stents and MB nozzle	Investigate feasibility of magnification of MB view	Jim P	dead	y		
			Where tweezers are needed implement tweezers with "stops" and soft tips	Teresa B Sue B	dead		x	
			Stop the action of picking up multiple stents at one time with tweezers	Teresa B Sue B	y			
MD	9	It is unknown if the mandrel size match up between EP and Riveting is a cause of mechanical damage	Implement temporary 100% inspect post EP 5 lots	Jim P		y		
			Oder .080" tubing for Microblasting for better fit	Dave				
			Review data and determine next action	Jim P John R		x		

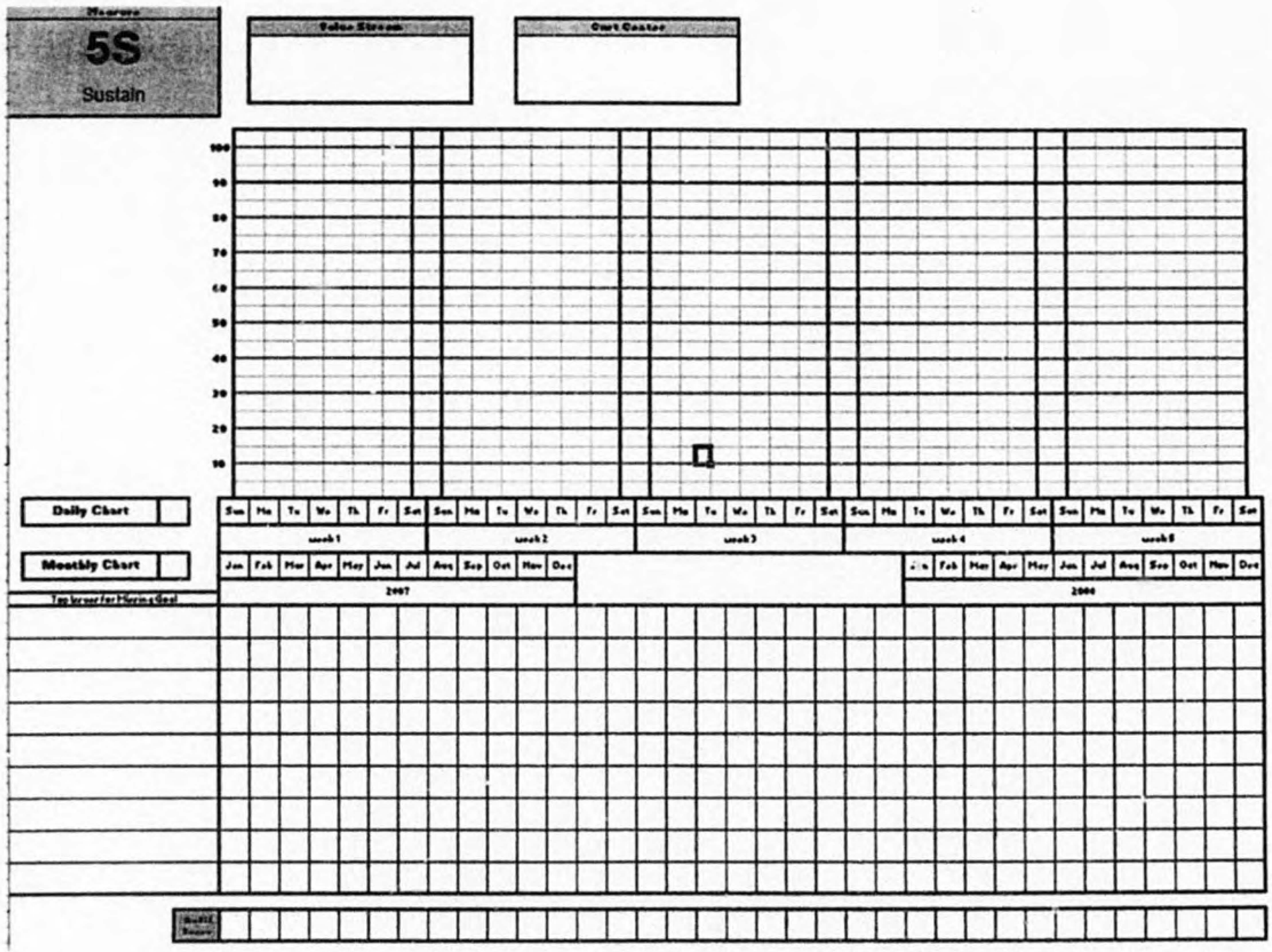
APPENDIX G

Auditing Form

Value Stream:			Cell/Line:			
Date:	**5S's Compliance Audit - Areas of Focus**					
5S Element	**Question Y = 4 Points N = 0 Points**	**Documentation**	**Work Area**	**Machines**	**Tools & Fixtures**	**Raw & WIP Components & Supplies**	**Score (20 points possible)**
Sort	**Are all unnecessary items removed from area?**	Y / N	Y / N	Y / N	Y / N	Y / N	
	Example:	Excess documents	Debris on the floor, equipment, work stations Personal belongings	Excess equipment	Excess tools/fixtures	Excess Raw & WIP components or supplies	
	Comments/ Corrective Action:						
Simplify	**Are all necessary items clearly identified and properly stored?**	Y / N	Y / N	Y / N	Y / N	Y / N	
	Example:	Manufacturing documentation	Aisles, drop off & pick up locations, garbage containers, scrap	Equipment	Tools/fixtures	Storage cabinets, POU shelves & containers	
	Comments/ Corrective Action:						
Sweep	**Are work areas, tools/fixtures, & equipment clean & in good working condition?**	Y / N	Y / N	Y / N	Y / N	Y / N	
	Example:	Stamped correct, in a "protector", all pages in place, and document(s) complete	Floors & workstations	Equipment	Tools/fixtures	Storage cabinets, POU shelves & containers	
	Comments/ Corrective Action:						
Standardize	**Has a process been established for sustaining the first 3 S's (5S Checksheets and/or visual documentation showing how area should look)?**	Y / N	Y / N	Y / N	Y / N	Y / N	
	Example:	Standard procedures established Performance board established	Material Flow visual, NCMR locations marked, scrap identified	Equipment Status communication established	5S's Standards have been developed	Replenishing and movement signal procedure established for all materials	
	Comments/ Corrective Action:						
Sustain	**Are the first 4S's being sustained?**	Y / N	Y / N	Y / N	Y / N	Y / N	
	Example:	Documentation requirements being followed and Performance Board Current	Labels, signs and area demarcations are maintained	Equipment Status Boards Current	5S's Standards are being followed	Material quantities conform to posted quantities & in proper storage location	
	Comments/ Corrective Action:						
20 to 36 - Little or No 5S Apparent (Level 1)		60 to 76 - Meets Minimal 5S Requirements (Level 3)		90 to 100 - Meets Most 5S Requirements (Level 5)		**Total Points 100 Possible**	
40 to 56 - Meets Some 5S Requirements (Level 2)		80 to 86 - Meets Several 5S Requirements (Level 4)					
Audit Team Members:							
Follow-up Actions & Final Comments:							

APPENDIX H

5S Auditing Form


5S
Sustain
Daily Chart
Monthly Chart
2007