Lab Quality Confab 2008:

Attacking Pre-Analytical with all the Lean Six Sigma Methods

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Session Objectives

- **Explore how Lean and Six Sigma tools complement each other.**
- **Understand how to translate the Lean Tool-Kit into a strong foundation for Continuous Improvement.**
- **Discover how to do a Rapid Lab Assessment in your own laboratory.**
- **Become skilled at turning Value Stream Maps into Detailed Action Plans.**
- **Learn to "Make it Stick" by creating a culture of standardized work that is not satisfied with being "good enough."**
- **Learn the best way to orchestrate a successful Kaizen Event.**
- **Discover the four stages to Managing Change and how to lead your staff through them.**

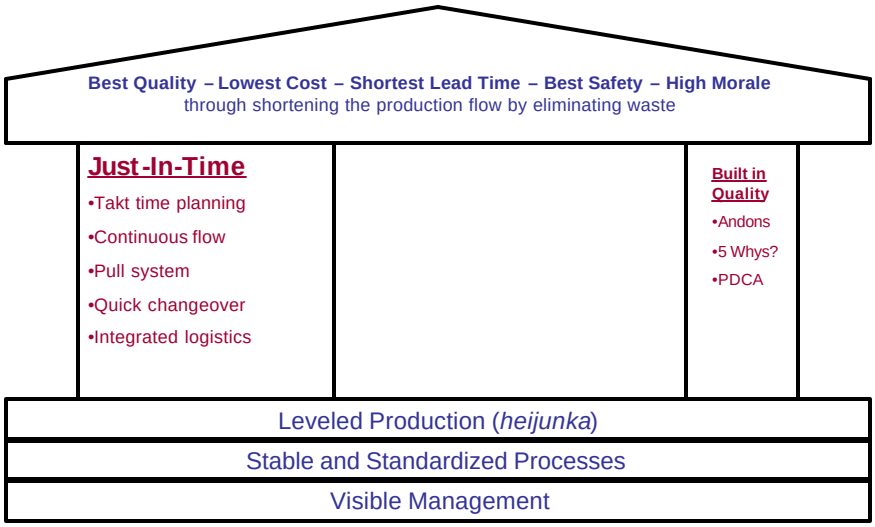
Approaches to Lean-Six Sigma

- Lean Bias
- Six Sigma Bias
- Separate but equal tool sets
- Integrated Lean and Six Sigma tool sets
- Beyond tools to philosophy-- Toyota

Lean and Six Sigma Similarities

- Customer and process focused
- Systems thinking
- Systematic problem solving
- Systematic waste (variation) reduction
- Establishment of customer and supplier relationships
- Establishment of customer expectations
- Improvements through experimentation
- Continuous improvement

Lean Tools Bias



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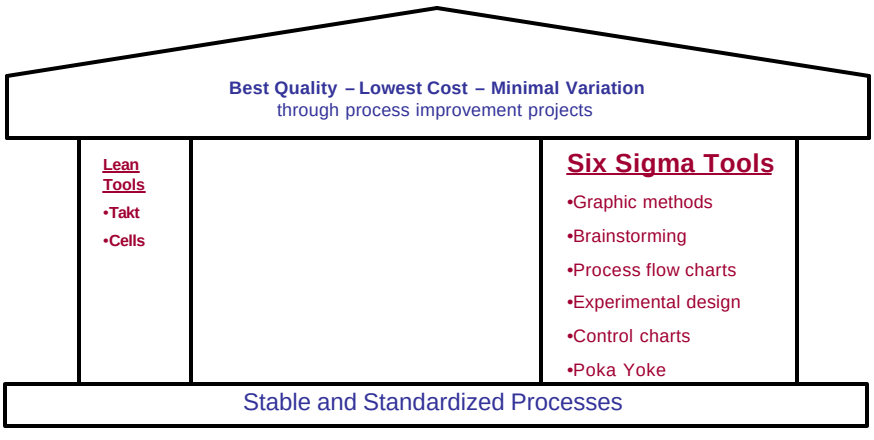
Six Sigma Bias



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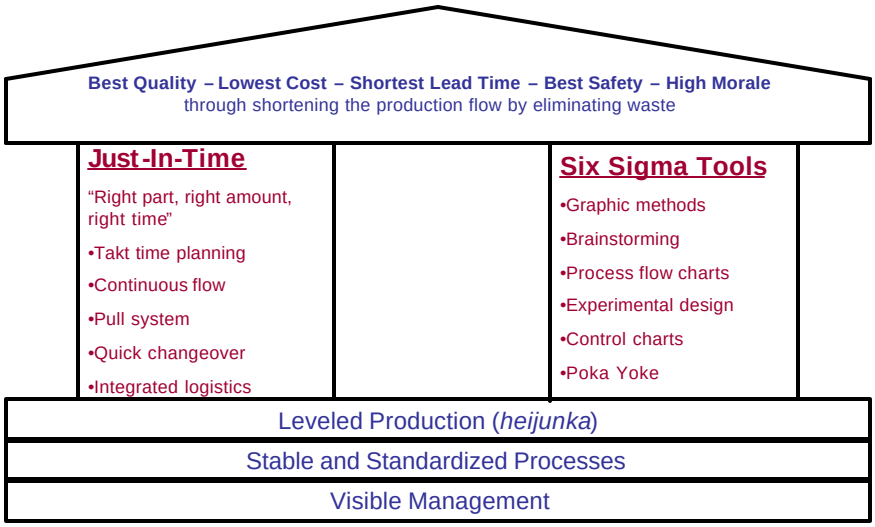
Separate but Equal Tool Sets



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What is Six Sigma?

- **Focuses on the customer**
- **Driven by fact and data**
- **Eliminates defects**
- **Reduces special variation**
- **Improves customer satisfaction**
- **Requires collaboration**
- **Zero defects**

The Drive for Perfection!

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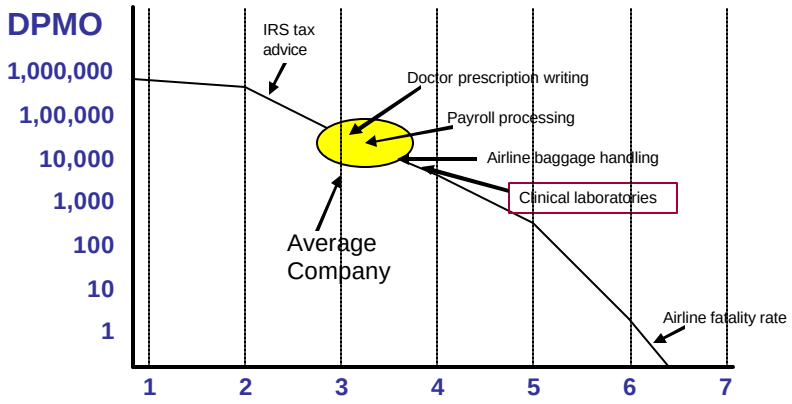
Where Does the Laboratory Industry Stand?



Sigma Scale of Measure

The Practical Meaning of Six Sigma

- **Where are labs on the Sigma Scale?**
  - **On average: 3.8 sigma[1]**
- **What, exactly, does that mean?**
  - **There were 5.621 billion lab tests performed in the United States in 2000[2]**
  - **3.8 sigma = 99% accuracy or 1% error rate**

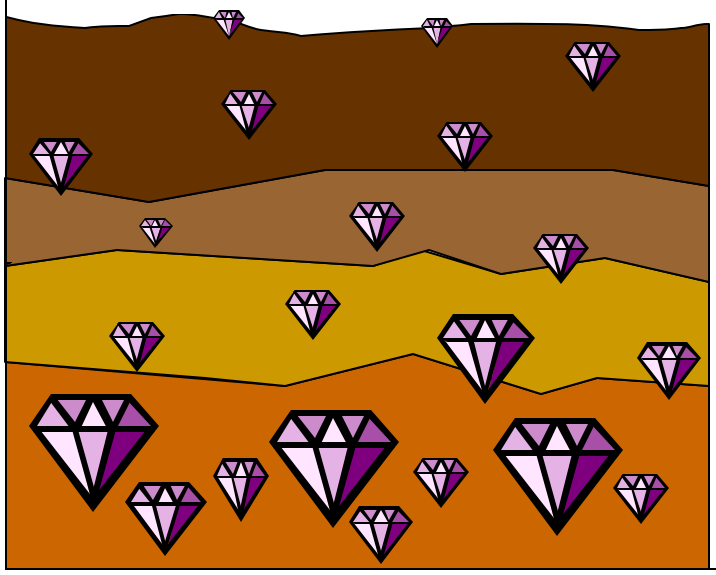
? 5.621B x 0.01 =

56.21M erroneous test results per year =

6,417 erroneous test results per hour !!!

1. Centers for Disease Control, Institute for Quality in Laboratory Medicine, 2004. 2. Laboratory Market Leaders Report, Washington G-2 Reports, 2001.

Finding the Gems of Six Sigma



3 Sigma- *Logic & Intuition*

Gems laying on or near the surface

4 Sigma- *Improve Process*

Gems just below the surface

5 Sigma- *Optimize Process*

Dig a little harder

6 Sigma- *Improve Designs*

Best and Most Gems buried deep in the organization

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Six Sigma Roadmap– DMAIC Methodology

Define

- Determine Current State
- Define Critical to Quality Metrics & Goals
- Define Project Scope
- Establish Project Charter

Measure

- Determine Key Input/Output Variables
- 6 M's- Methods, Manpower, Machines, Materials, Measurement, Mother Nature
- Calculate Initial Process Capabilities
- Establish Baseline

Analyze

- Evaluate Existing Control Plan Using Statistical Methods to Determine Potential Key Inputs (X)
- Prioritize Key Input Variables
- Establish Y = f(X)

Improve

- Verify Key Inputs with Design of Experiments
- Generate Improvement Ideas
- Determine Optimum Settings

Control

- Update Control Plan
- Verify Improvements
- Sustain the Gains

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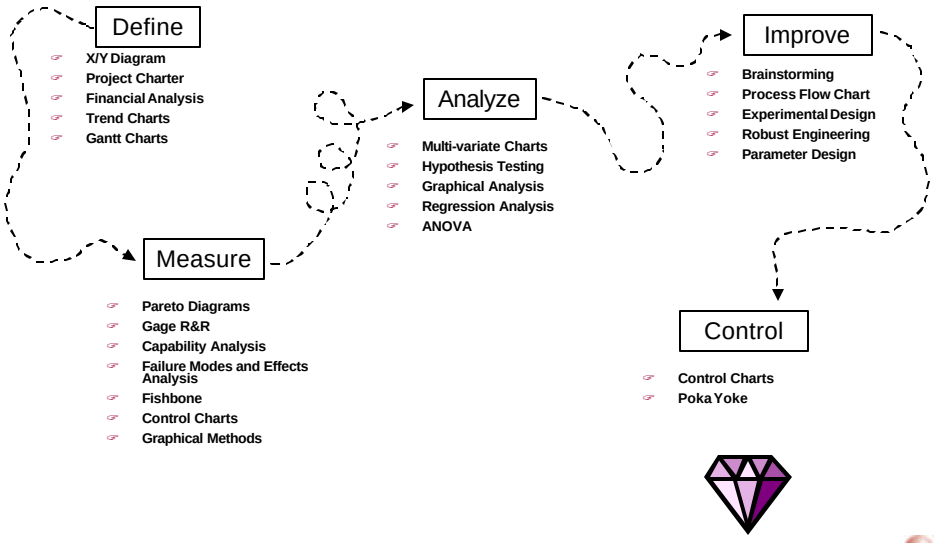
Six Sigma Roadmap– DMAIC Tools



Why does Six Sigma "need" Lean?

- Lean identifies waste
- Lean improves speed
- Specific speed tools – 5S, continuous flow
- Methods for rapid action – Kaizen
- Approaches d sigma if NVA steps are eliminated
- Dell, Southwest Airlines

Why does Lean "need" Six Sigma?

- Critical to achieve and sustain results
- Ensures customer CTQ is front and center
- Biggest waste of all - lost customers
- Recognizes impact of variation
- ISO 9000
- Re-engineering
- Sony, Fedex

How Are They Used Together?

- Lean trains eye to SEE
- Six Sigma helps reduce variation
- Ask:
  - Which steps are really necessary?
  - What's meaningful?
  - Which things add NO benefit?
- Speed and quality are linked

Characteristics of Integrated Lean Six Sigma

- Driven by the Value Stream vision
- Focus on creating flow
- Implementation plan
  - Big hitters first? (Pareto diagram)
  - Loop by loop?
- Use the simplest tools appropriate for the problem
- Separate "do its," kaizen events, Six Sigma projects and engineering projects
- Experts trained in Lean and Six Sigma (pull out appropriate tool for each situation)
- Bottom up involvement in improvement projects
  - Start with the people performing the work

Synergies of an Integrated Approach

- The Lean Value Stream approach identifies opportunities for improvement.
  - Seeing the whole picture makes the wasted motion, material and actions more apparent
- The Six Sigma data driven approach prioritizes and addresses the identified opportunities.
- Enables the knowledge of how and when to apply the correct methodology and tools to the right opportunity.
- Establish a link between Lean flow, velocity and inventory and Six Sigma variation reduction.

Synergies of an Integrated Approach

- Lasting organizational benefits of a culturally driven, behavior-based approach, augmented with data driven discipline.
  - Everyone in the organization knows that part of their job is to make their job easier and more productive.
- A Value Stream approach to run the entire business with a sophisticated problem solving methodology to apply when necessary.
  - The Value Stream Maps and the Action Plans associated with them enable upper management to monitor the critical to quality and critical to cost issues in the lab.

Typical Six Sigma Implementation

Early in Deployment

- Driven by dedicated Black Belts
- Function outside their home departments

Continuing Stages of Deployment

- Growth in the number of Green Belts
- Green Belts function in their own departments
- Improvement is driven by a mix of Black Belts and Green Belts

Mature Deployment

- Most of the improvement is driven by non-dedicated Green belts
- Black Belts become enablers of Green Belt projects

Typical Lean Implementation

- Improvement occurs in the lab and is mostly implemented by the lab scientists.
- Skill sets develop and culture evolves over a long period of time.
- Sensei role in "learning by doing".
- Emphasis on rapid implementation and use of the simplest tools.
- Work toward a culture of bottom up improvement.

An Ideal State for Lean Six Sigma Implementation

- Lean thinking and behaviors are engrained across the organization
- Value Stream management is deployed to achieve process oriented systems thinking
- Six Sigma Green Belt skill level is attained by everyone in the organization
- The organization is stable enough to warrant improvement as a daily activity within the laboratory workflow

An Ideal State for Lean Six Sigma Implementation

- A small number of Black Belts and Master Black Belts are reserved for chronic, high-value projects
- Black Belts serve primarily as teachers and trainers
- The culture changes to one where everyone's job is continuous improvement
- The new structure is outlined in the organization's business operating system

Case Study Using Lean and Six Sigma Tools

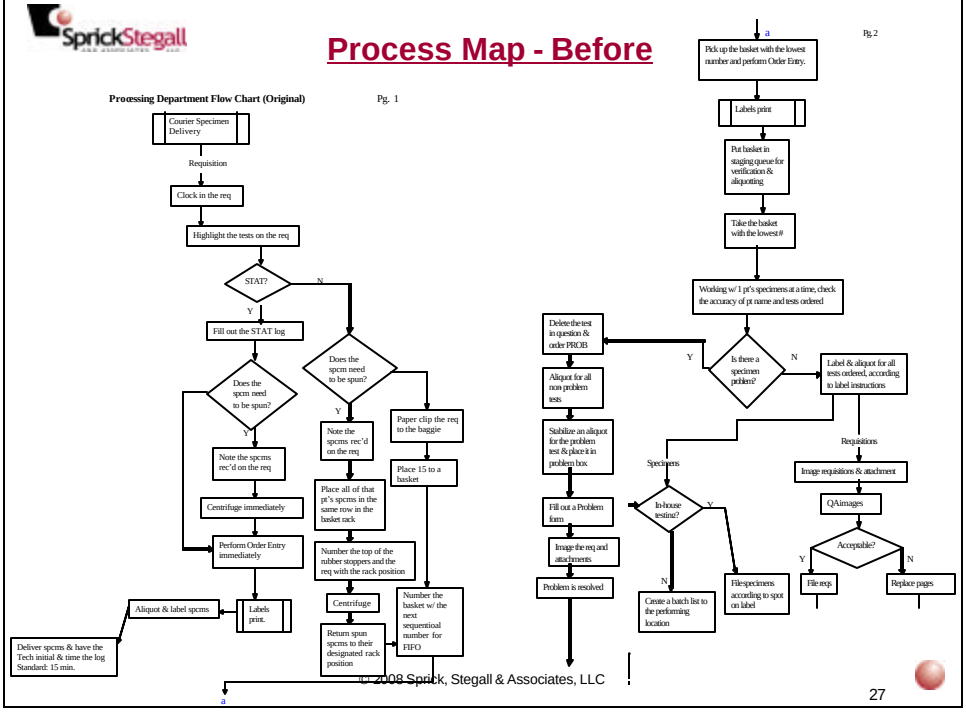
Up and Coming (UAC) Laboratory

- Performs 4M tests annually
- Receives 3,000 requisitions daily
- Physician offices and system hospitals
- Massive dump every evening
- Problems in long receiving delays testing and creates overtime expense
- Work group chartered to improve workflow

Step 1: Define

- "There's no problem here!"
- Department is well-organized
- Visible signs of management control
- Processes in baskets of 30 specimens
- Decided to flow chart the process to identify bottlenecks
- Who are the customers?

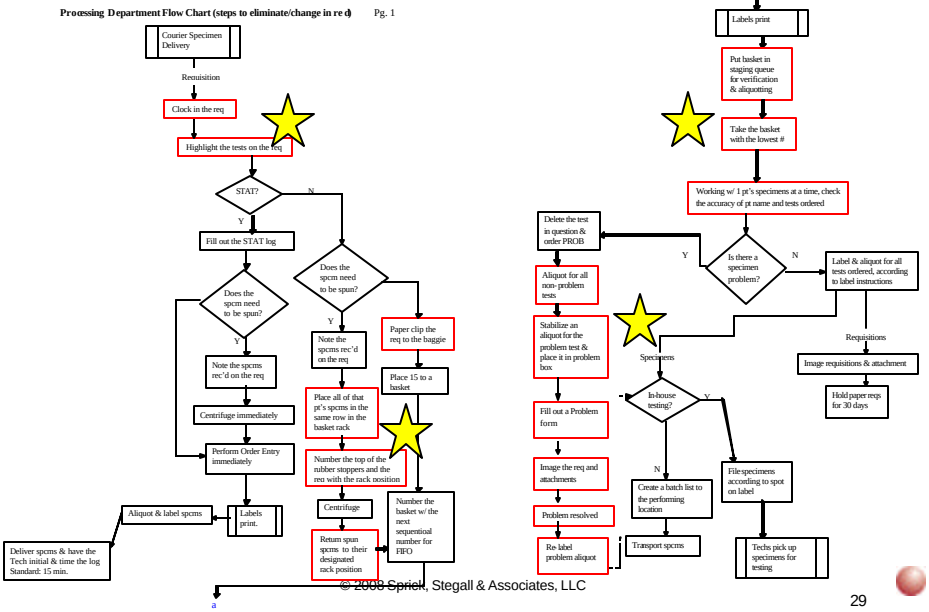
Process Map - Before



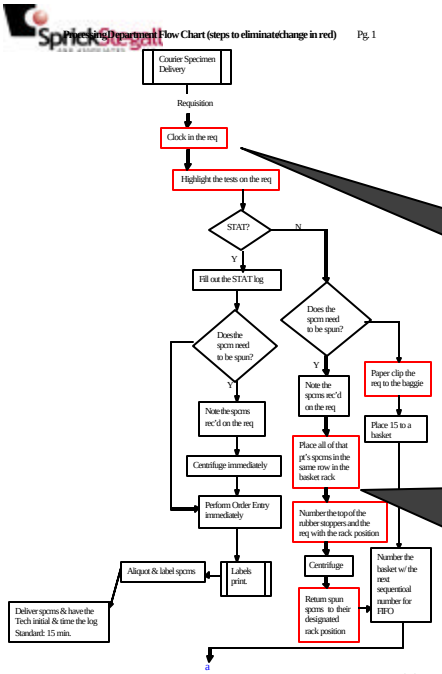
Step 2: Measure

- **No data collected to monitor performance from customer's perspective**
- **"Do you work at your convenience or your customer's?"**
- **Didn't know the lead time of a single specimen!**
- **Worked in batch mode - FIFO**

NVA Steps Exposed



NVA Steps Exposed



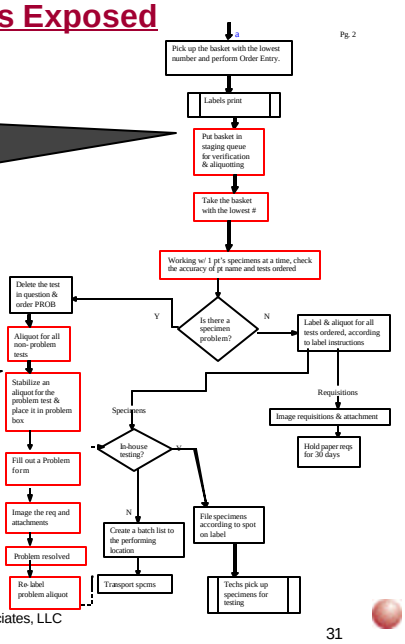
These steps add no value to the customer!

Identified manual steps that delayed the processing cycle time as long as 3 hours!

NVA Steps Exposed

Large batch size causes delays in delivering samples to the analytical areas!

Rework causes a big delay in the production flow!



Step 3: Analyze

- Baseline data was tallied manually
- Cycle time stays below 100 minutes, except at peak capacity
- Could special variation be reduced by redesigning workflow?
- Could workflow be improved by redesigning work stations?

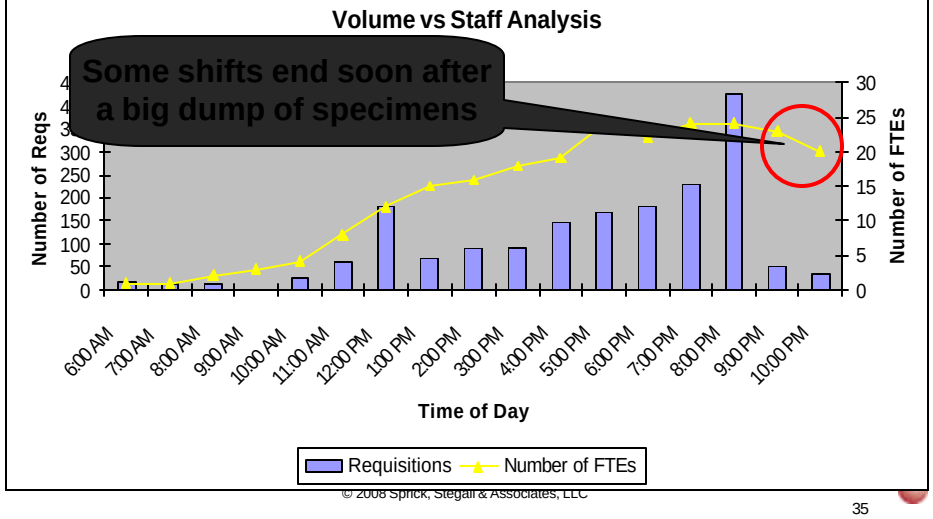
What is CTQ?

- Critical to keep the line moving
- Take offsite any situation that causes a delay in the production flow (not to Lean yet!)
- Key performance indicator is basket cycle time of 120 minutes
- Rework goal = 5 Sigma

Define COPQ

- Lengthy rework
  - Takes 20 min apiece
  - Salaries est $10.00 / hour
  - Rework rate of 5,984 / month
- Current Sigma Level = 3.8
- Cost of Poor Quality is $236,966 annually
- Savings from reducing rework loops could fund automation for the department

Staffing Analysis



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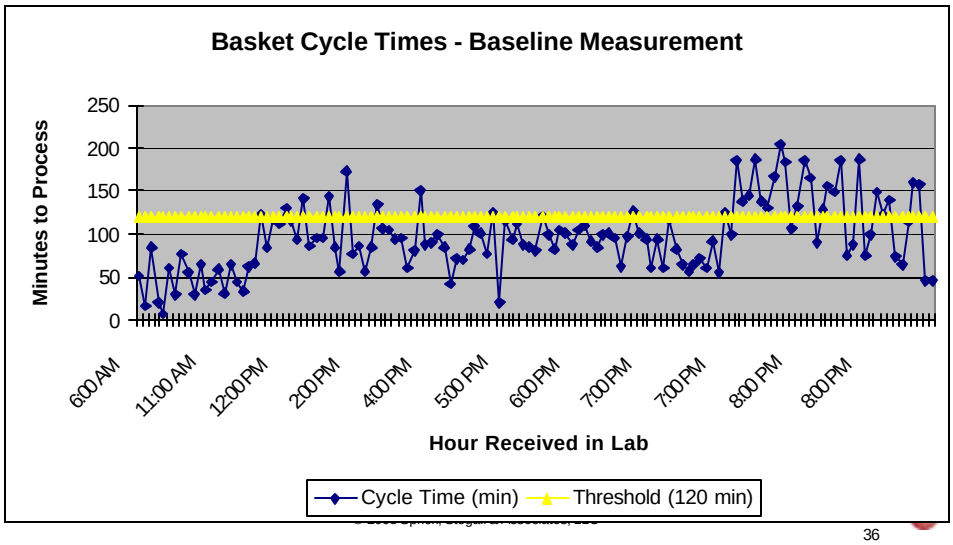
Baseline Cycle Times



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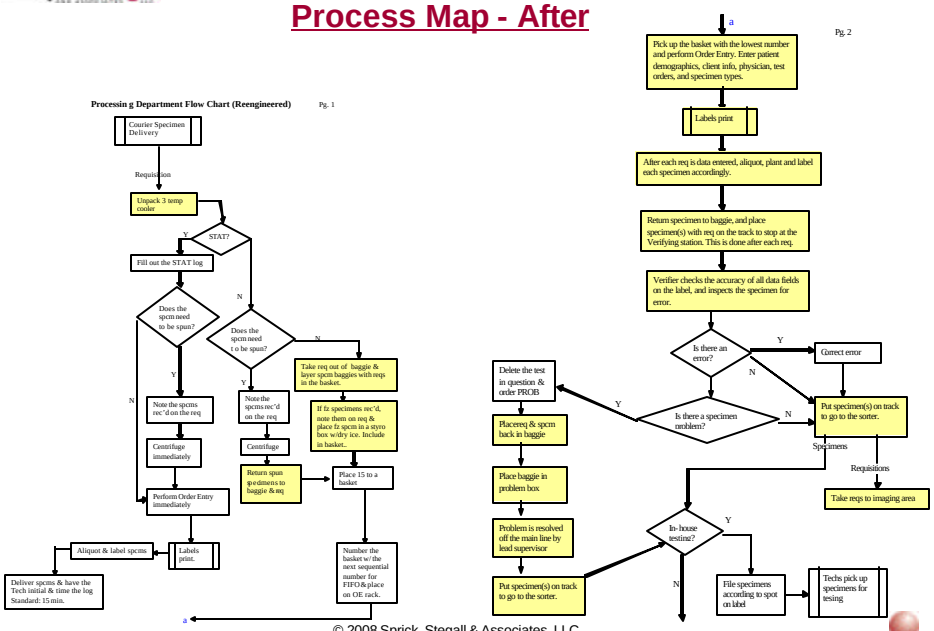
Step 4: Improve

- Important to redesign process first and create work cell to fit the flow
- Liked process enough not to start over
- Evaluated three options for new work cells
- Selected option that allowed for most efficient use of space and room to grow
- Implemented new workstations
- Adjusted shifts to align with workload

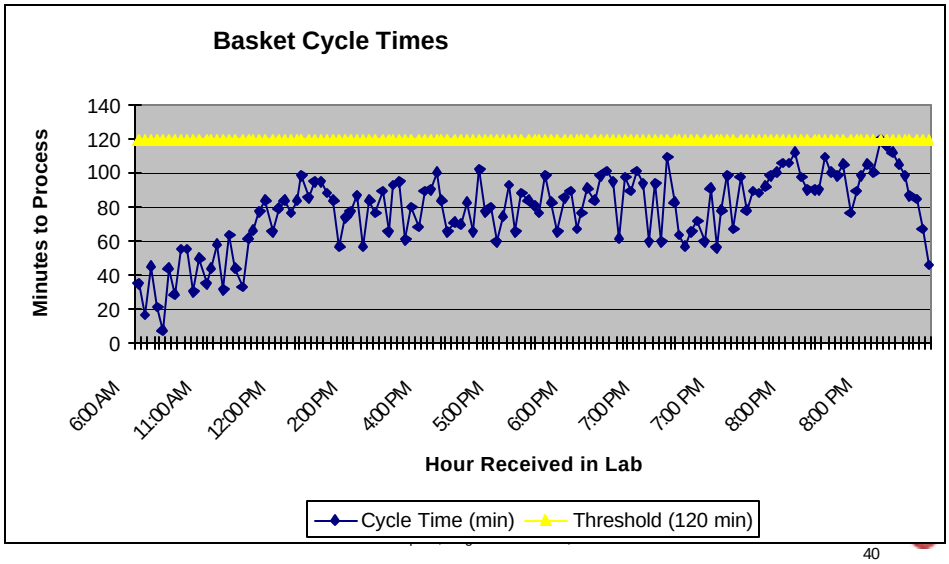
Process Map - After



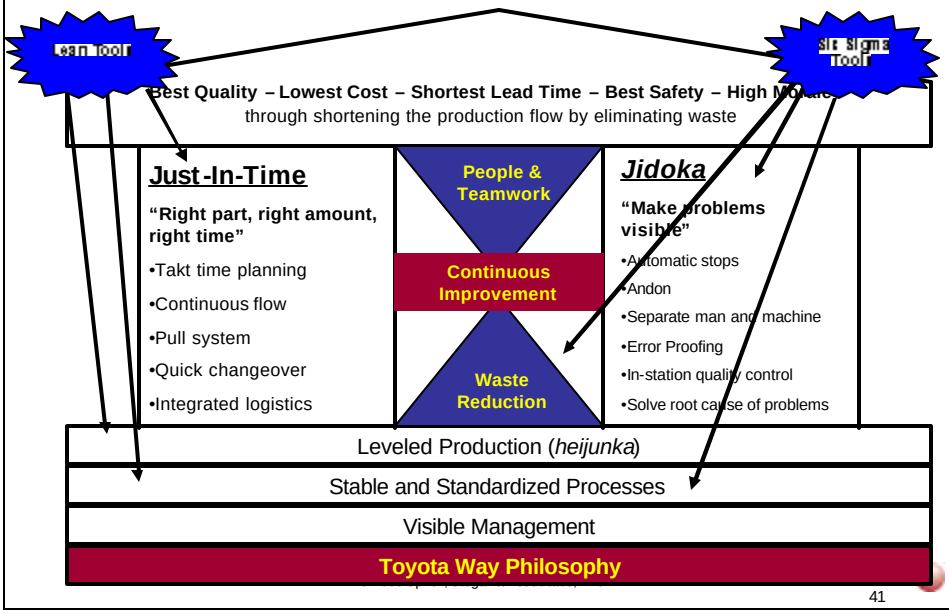
Step 5: Control

- Created a LIS report to track basket cycle time
- Measure progress now on a weekly basis
- Sustain the gain by posting cycle times in the department

Post Redesign Cycle Times



The Toyota Production System



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The "Big Ten Tools" for Implementing Kaizen Bursts

Tools:

1. **Developing 'eyes for waste'**
2. **Value Stream Mapping**
3. **Quick problem solving**
4. **Standardized work**
5. **5S and visual management**
6. **One piece flow cells, pull systems, and right sized equipment.**
7. **Quick Set up and Changeover**
8. **Andons and Error proofing**
9. **Jidoka (person/machine separation)**
10. **Total Productive Maintenance**

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The "Foundation" Tools

Tool #1 - Lean Lab Assessment

- **Enables the identification of strengths and weaknesses in a relatively short time.**
- **Can be used as a Lean baseline for process improvement (kaizen events).**
- **Adapted for laboratories from Goodson's article—*Read a Plant Fast.***

Assessment Tools

1. Lean Lab Assessment Rating Sheet
   - 11 categories that parallel Lean transformation action plans; focuses on what can be seen. (Discuss concept of "learning to see")
   - The average score for service organizations is 56.
     - A world class rating is 121 points.
2. Form 2: Lean Lab Assessment Questionnaire
   - 20 questions that assess the 11 categories on the Rating Sheet.
   - The average number of Yes's for service organizations is 6/20.
     - A world class rating is 20 yeses.
3. Tube Travel Diagrams
4. Spaghetti Diagrams

Lean Lab Assessment

- The tour process relies on teams trained to assimilate visual information.
  - Learn to see.
  - Assign team members to specific categories.
  - Team members must understand basic Lean concepts.
  - Team discussions and consensus determine ratings.
- Can be used as a training tool.

Lean Lab Assessment

- How to Conduct One:
  - Form a team with a leader
  - Train the team in Lean concepts and the Lean Lab Assessment process.
  - Assign team members specific categories.
  - Tour the laboratory (or plant) without taking notes.
  - Immediately complete the two forms: Lean Lab Assessment Rating Sheet and Yes/No Questionnaire.
  - Write down the rationale for ratings.
  - Agree on change priorities and actions.

The Seven Wastes

- What do you look for?
  - Overproduction– unnecessary batch testing
  - Correction– repeats, errors, work in process that lacks key components
  - Motion– how many steps are involved?
  - Material Movement– how often is the specimen or reagent moved?
  - Waiting Time– how long does the specimen sit before testing?
  - Inventory– is it appropriate for the level of testing?
  - Processing– efforts that add no value from the customer's point of view

Current State Assessment: Current Wastes

- Waste of Processing
  - No FIFO system
  - Separate rooms for Sorting, Registration & Order Entry
  - Separate job duties for Registration & Order Entry
  - Pulling reqs to sort specimens from couriers
  - Writing Star account numbers on reqs
  - Counting requisitions (15 per bin)
  - Flipping coversheets
  - Filing requisitions
  - Stopping to call for missing information
  - Too many old requisitions in use
- Waste of Inventory
  - Multiple waiting stages for processing
  - Too much supplies piled up
  - Supplies scattered and disorganized
  - Need to 5S

Current State Assessment: Current Wastes, con't.

- Waste of Waiting
  - Waiting for reqs to go to Registration
  - Waiting for reqs to come back from Registration
  - Signing in specimens (fluids, bone marrows)
  - Slow response time from label printer
  - Waiting for couriers to drop off specimens
- Waste of Motion
  - Staff milling about: miscellaneous reasons for staff to move off their stations (get more work, move bins, make copies, solve problems, etc.)
  - Moving specimens around before they go to the lab
  - Computer stations all over the lab for Order Entry
  - Not enough/correct materials at workstations

Current State Assessment: Current Wastes, con't.

- Waste of Production (Over- or Under-)
  - Staff leaving workstations too frequently
  - Batching and counting reqs
  - Work not moving through (due to problems)
  - Holding finished work at Order Entry
- Waste of Transport
  - Moving reqs back and forth
  - Moving bins around to Registration and Order Entry
- Waste of Defects
  - Separating reqs from the samples
  - Workers working differently in the same job
  - Mislabeled specimens
  - Lost specimens
  - Missing tests on reqs
  - Ordering wrong tests

The 5S's: Sort, Stabilize, Shine, Standardize and Sustain

- Have they applied 5S to their work environment?
  - **Sort:** Go through everything in the work area, separating and eliminating what isn't needed.
  - **Stabilize (Set in Order):** Arrange items that are needed in a neat, consistent and easy-to-use manner.
  - **Shine:** Clean up the work area, equipment, and tools.
  - **Standardize:** Organization, order and cleanliness are built into the work routine in a standardized fashion, company-wide.
  - **Sustain:** Inspection ready work environment, day- in and day-out.

Form 1: Lean Lab Assessment Rating Sl

Rated by:_____ Rapid Lab Assessment Client_____
Tour Date:_____ Table 1 Rating Sheet Operation _____

	Ratings →	Poor	Below Average	Average	Above Average	Excellent	Best in Class	
No.	Measure ↓ Score →	1	3	5	7	9	11	Scores
1	Customer satisfaction							
2	Safety, environment, cleanliness, & order							
3	Visual Management System							
4	Scheduling System							
5	Space use, material movement, & product flow							
6	Inventory & WIP levels							
7	Teamwork & Motivation							
8	Condition & maintenance of tools & equipment							
9	Management of complexity & variability							
10	Supply Chain Integration							
11	Commitment to Quality							
	TOTALS →							

Form 1: Lean Lab Assessment Rating Sheet

1. **Customer Satisfaction (questions 1, 2, 20)**
   - **The laboratorians know who their customers are– both internal and external– and customer satisfaction is their primary goal.**
   - **The laboratorians understand that it's their job to make tours an exceptional experience for the client so that they leave with positive feelings for the lab and the services it performs.**
   - **Visitors should be welcomed and given information about the lab layout, workforce, customers, & services.**
   - **Quality and customer satisfaction ratings should be prominently displayed**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

2. **Safety, environment, cleanliness, & order (5S) (questions 3-5, 20).**
   - **Specimens move safely and efficiently through the laboratory. Safety records are displayed.**
   - **Inventory is easy to count and estimate.**
   - **The laboratory is clean and orderly. It is well lit, has good air quality, and has low noise levels.**
   - **A visual labeling system marks inventory, tools, processes and flow.**
   - **A place for everything and everything in its place.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

3. **Visual Management System (questions 2, 4, 6-10, 20).**
   - **Visual cues and directions are readily apparent.**
   - **Work instructions, quality charts, productivity charts and maintenance charts are posted.**
   - **A central control room or status board shows the current state of operations in the lab.**
   - **Operational goals and performance measures are posted.**
   - **Workcell inventory levels are controlled and stored properly.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

4. **Scheduling System (questions 11, 20).**
   - **The "pacemaker process" has been identified for each workcell and it determines the rate of flow through the cell.**
   - **Inventory levels are kept at appropriate levels for the pacemaker.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

5. **Use of Space, Movement of Materials, and Specimen Flow (questions 7, 12, 13, 20).**
   - **Specimens and testing materials are stored in or near the workcell.**
   - **Tools and equipment should be kept where they are used.**
   - **The lab is laid out in continuous flow cells, not in traditional silos.**
   - **The lab layout minimizes the number of steps that must be taken during performance of the testing.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

6. **Levels of Inventory and Specimens in Progress (questions 7, 11, 20).**
   - **Inventory in the workcell should not exceed the level needed for one shift.**
   - **The pacemaker process is being used to determine proper inventory levels.**
   - **Specimens are promptly stored when testing is completed.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

7. **Teamwork and Motivation (questions 6, 9, 14, 15, 20).**
   - **Laboratorians consistently focus on productivity and quality goals.**
   - **Laboratorians are well trained and eager to share their knowledge and experience with customers and visitors.**
   - **Safety and environmental rules are clearly displayed.**
   - **Problem solving and employee empowerment procedures are posted– clear indicators of teamwork.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

8. **Condition and Maintenance of Equipment and Tools (questions 16, 20).**
   - **Equipment and instruments are kept clean and are well maintained.**
   - **Purchase dates and costs are stenciled on the side of the instruments.**
   - **Maintenance records are posted.**
   - **Employees are involved in purchasing tools and equipment.**
   - **Laboratorians are freed from having to "baby-sit" instruments.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

9. **Management of Complexity and Variability (questions 8, 17, 20).**
   - **Quality controls are automatically recorded.**
   - **Quality specifications and work instructions are prominently posted.**
   - **Instruments signal when something is wrong.**
   - **Supplies are kept at a minimum and variety is minimized as much as possible.**
   - **The systems are designed to prevent errors.**

Form 1: Lean Lab Assessment Rating Sheet (cont.)

9. Supply Chain Integration (questions 18, 20).

- The lab works closely with suppliers to keep inventory levels low.
- The number of suppliers is limited, but reliable.
- Suppliers are certified for quality, delivery and cost performance.

Form 1: Lean Lab Assessment Rating Sheet (cont.)

11. Commitment to Quality (questions 15, 17, 19, 20).

- The laboratorians are constantly looking for better ways to do their jobs.
- Quality and productivity measures are displayed in each workcell.
- Process improvement initiatives are well planned and implemented in a timely fashion.
- Systems have been designed so that it is harder to do things the wrong way.
- Short-term and long-term goals for the lab and the team are posted.
- Customers are frequently surveyed about the quality of work coming out of the lab and the survey results are posted.

Form 1: Lean Lab Assessment Rating Sheet (cont.)

11. Commitment to Quality (questions 15, 17, 19, 20) (cont.)

- Lab should have a central history of all problems encountered and how they were disposed of.
- Motivated, trained teams at all levels of the organization.
- Problem solving is everybody's job.
- Teams understand marketing responsibilities.
- Quality measures are visible.
- Team objectives and performance are posted.

Form 1: Lean Lab Assessment Rating Sheet (cont.)

11. Commitment to Quality (questions 15, 17, 19, 20) (cont.)

- Kaizen bursts are continually proposed and applied.
- Formalized problem solving methodology in place.
- Standardized work & training.
- Staff teams support work teams.
- Current and future state process maps.
- Fail-safe methods are continually applied to all processes.
- Visual controls in place and utilized.
- Continuous improvement displays; benchmarking.
- Supplier involvement in test development.
- Six Sigma, ISO-9000, or Lean certifications.

Form 2: Lean Lab Assessment Questionnaire

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Lab:	Rapid Lab Assessment Date	
No.	Table 2 Assessment Questionnaire	Yes/No
1	Are visitors welcomed and given information about lab layout, workforce, customers and tests performed?	
2	Are ratings for customer satisfaction and testing quality displayed?	
3	Is the facility safe, clean, orderly and well lit? Is the air quality good and noise level low?	
4	Does a visual labeling system identify and locate inventory, tools, processes and flow?	
5	Does everything have its own place and is everything stored in its place?	
6	Are up to date operational goals and performance measures for those goals prominently posted?	
7	Are production materials brought to and stored at line side rather than in separate inventory storage areas?	
8	Are work instructions and quality specifications visible in all work areas?	
9	Are updated charts on productivity, quality, safety and problem solving visible for all teams?	
10	Can the current state of the operation be viewed from a central control room, on a status board or on a CRT?	
11	Are testing lines scheduled off a single pacing process with appropriate inventory levels at each stage?	
12	Is material moved only once as short a distance as possible and in appropriate containers?	
13	Is the lab laid out in continuous product flow lines rather than in "departments"?	
14	Are work teams trained, empowered and involved in problem solving and ongoing improvements?	
15	Do employees appear committed to continuous improvement?	
16	Is a timetable posted for equipment preventive maintenance and continuous improvement of tools and processes?	
17	Is there an effective project management process, with cost and timing goals, for new product startups?	
18	Is a supplier certification process with measures for quality, delivery and cost performance displayed?	
19	Have key product characteristics been identified and fail-safe methods used to forestall propagation of defects?	
20	Would you buy the product this operation produces?	
	Total Number of Yeses	

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Form 2: Lean Lab Assessment Questionnaire

- **20 questions that gauge Lean implementation success.**
- **A "Yes" requires substantial implementation of the Lean concept implied by the question.**
- **The average number of Yes's is 6/20 for service organizations.**

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7	Are production materials brought to and stored at line side rather than in separate inventory storage areas?	
8	Are work instructions and quality specifications visible in all work areas?	
9	Are updated charts on productivity, quality, safety and problem solving visible for all teams?	
10	Can the current state of the operation be viewed from a central control room, on a status board or on a CRT?	
11	Are testing lines scheduled off a single pacing process with appropriate inventory levels at each stage?	
12	Is material moved only once as short a distance as possible and in appropriate containers?	
13	Is the lab laid out in continuous product flow lines rather than in "departments"?	
14	Are work teams trained, empowered and involved in problem solving and ongoing improvements?	
15	Do employees appear committed to continuous improvement?	
16	Is a timetable posted for equipment preventive maintenance and continuous improvement of tools and processes?	
17	Is there an effective project management process, with cost and timing goals, for new product startups?	
18	Is a supplier certification process with measures for quality, delivery and cost performance displayed?	
19	Have key product characteristics been identified and fail-safe methods used to forestall propagation of defects?	
20	Would you buy the product this operation produces?	
	Total Number of Yeses	

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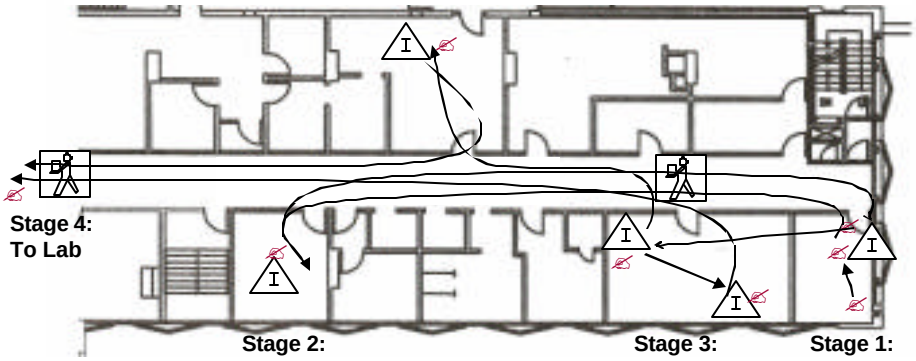
Current State Assessment: Tube Travel Diagram

- How do samples move through the work area and how many steps does it take to transport them from one stage to another?
- Total Steps = 366 steps
- All the staff was walking some or all of the route often: chaotic flow, lots of people walking about, difficult to see if ANY work was getting done



I = Holding (storage)

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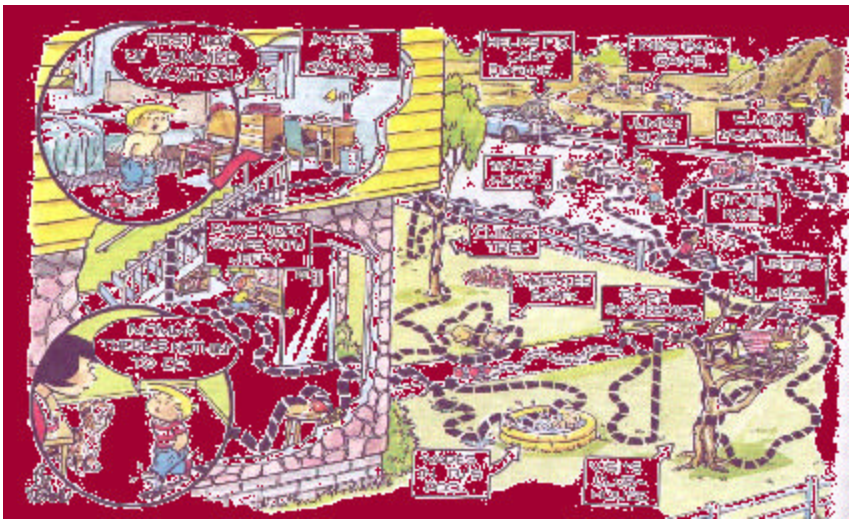
Billy is in Your Laboratory



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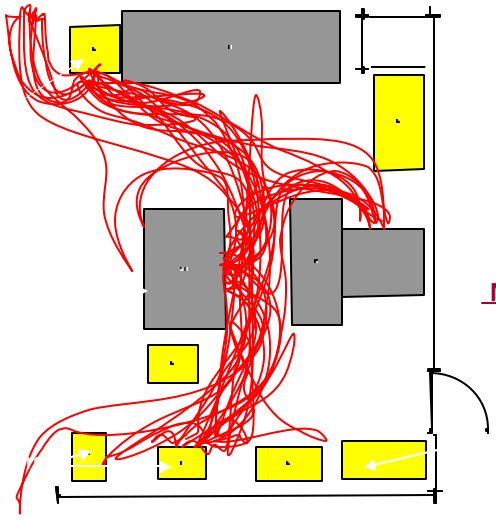
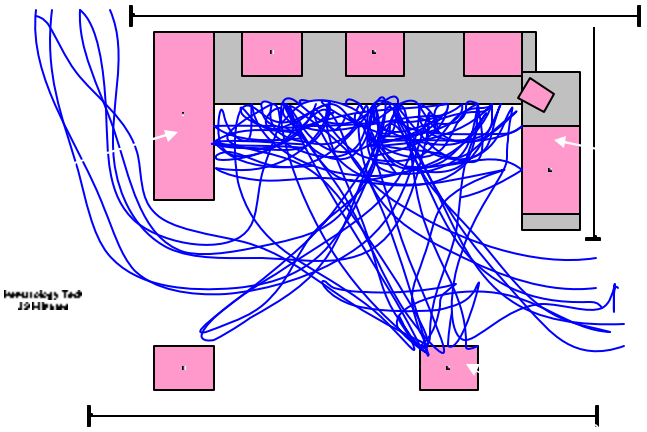
Billy is in Your Laboratory



Example of Chemistry Spaghetti Diagram: Non-value added wasted motion

Billy is in Your Laboratory

Example of Hematology Spaghetti Diagram:
Non-value added wasted motion



15 Minute Break

Tool #2 - Value Stream Mapping

- Value stream mapping (VSM) gives a broader perspective of your operations.
  - Allows visualization of the entire value stream so that unintended consequences can be minimized.
- VSM tailors events in the lab to fit with business process events and support efforts.

Value Stream Planning

- What is a Value Stream?
  - The flow of specimens from order entry or order receipt to result reporting.
  - The transformation of the specimen into clinical information.
  - The flow of information from order to report.
- A Value Stream Map uses simple graphics to depict the sequence, timing and flow of information, materials, specimens, and people.

Value Stream Planning

Defining the Current State:

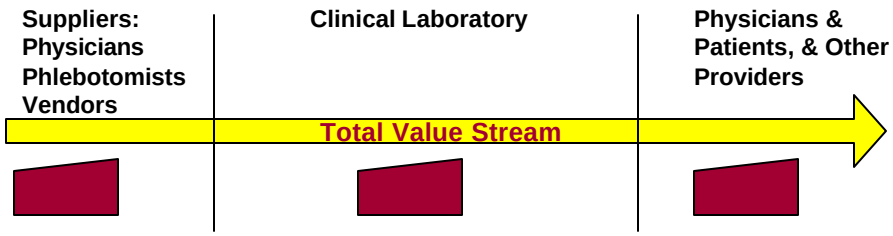
- You must 'Go and See'.
  - There is no substitute for personal observation when defining the current state map.
- You must develop 'Eyes for Waste'.
  - As you gain experience, the wasted materials and activities become more obvious.
- Involve the Laboratory Scientists in current state map making.
  - They already know the current state better than anyone.

Value Stream—What is it?

- "Whenever there is a product for a customer, there is a value stream. The challenge lies in seeing it."

  Value Stream Mapping Workshop, Participant Guide, The Lean Enterprise Institute.

- Definition: A value stream is all the actions (both value added and non-value added) currently required to bring a product through the main flows essential to every product:
  - The production flow from "raw material" into the arms of the customer; in lab lingo, from specimen to lab report or from patient to appropriate care and outcome.



Why value stream mapping is an essential tool

- Value stream mapping is the most important tool in the war to eliminate wasted time, effort and material
- More than just a single process—you see the flow
  - You see more than wastes—you see the sources of wastes
  - It provides a common language for talking about your processes
  - It makes wastes apparent, so you can discuss them
  - It ties together all lean concepts and techniques

Leaning to See by Mike Rother and John Shook, page 4.

Why value stream mapping is an essential tool

- It forms the basis of an implementation plan
- It shows the linkage between the information flow and the material flow.
- Value stream mapping is a qualitative tool by which you describe in detail how your facility should operate in order to create flow.

Leaning to See by Mike Rother and John Shook, page 4.

The value stream map teaches you, your managers, suppliers, and customers to see value, differentiate value from waste and to get rid of waste. (Jim Womack)

Value Stream Mapping

- **Production Flow:**

Information Flow:
Results &
Orders

Resource Flow:
Specimens
Supplies
Reagents
People

Value Stream Mapping—Product Families

- **Create a matrix with processing steps and equipment on one axis and the service lines on the other. See an example below:**

	Example: Processing Steps & Equipment											
	1	2	3	4	5	6	7	8	9	10	11	12
Services	Phlebotomy	Receipt	Centrifugation	Aliquot	Bar-code Labeling	Distribution	Place on Instrument & Cycle	Sample Prep	Sample Staining	Distribution	Reading	Reporting
Chemistry	x	x	x	x	x	x	x					x
Immunology	x	x	x	x	x	x	x					x
Urinalysis		x	x	x	x	x	x					x
Coagulation	x	x	x	x	x	x	x					x
Hematology	x	x			x	x	x	x	x	x	x	x
Flow Cytometry	x	x			x	x	x			x	x	x
Microbiology		x			x	x	x	x	x	x	x	x
Cytology-Non-GYN		x	x	x	x			x	x	x	x	x
Histology		x			x	x	x	x	x	x	x	x
Cytology: GYN		x			x	x	x	x	x	x	x	x
Frozens		x			x	x	x	x	x		x	x

Value Stream Mapping—Product Families (cont.)

- Identify the product families
- Select a product family to analyze based on your business situation
- Useful criteria may include the following:
  - Service line (product family) produces highest volume in units or costs,
  - Service line (product family) has the highest defect rate, poorest quality,
  - Service line (product family) that uses the most processes, or
  - Service line (product family) that has highest customer demand.

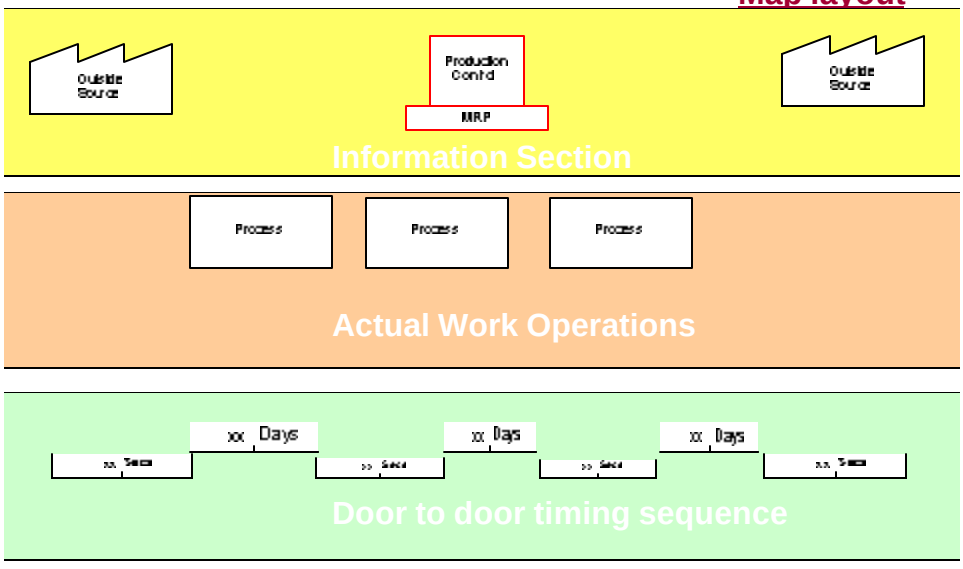
Value Stream Mapping—Overview of the Process

- A paper and pencil exercise, use lean flowcharting icons
- Begin with the customer report and work backwards
- Consider the following questions:
  - How does your product get from the last step in your testing process to the customer?
  - Where is the pacemaker process, i.e., technical testing area?
  - How are orders transmitted to the pacemaker process?
  - How are materials (specimens, supplies, reagents, and consumables) supplied to the testing areas?
  - How are materials obtained by the testing areas?

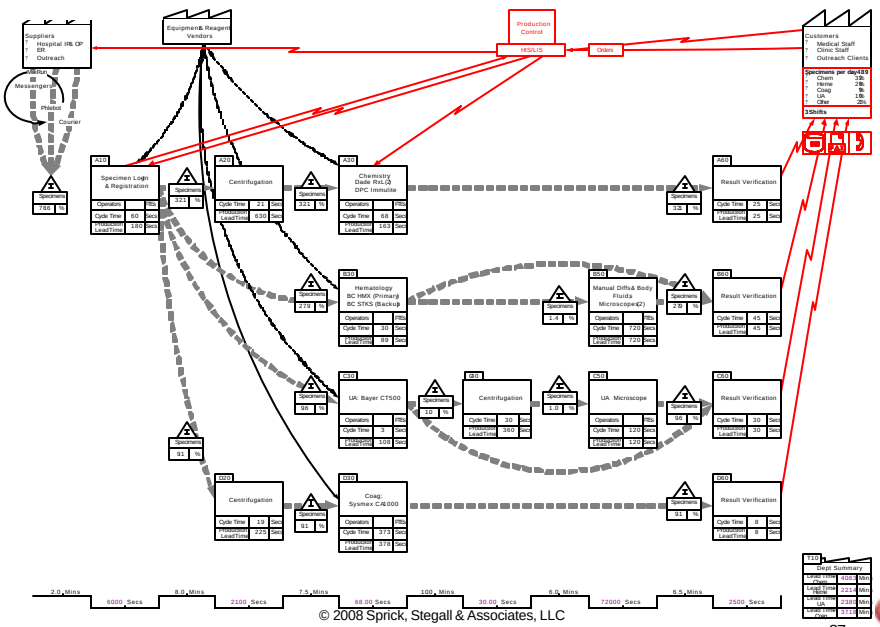
Value Stream Mapping—Overview of the Process (cont.)

- How are materials (specimens, supplies, reagents, and consumables) supplied to the upstream processes?
- What is the relationship between a customer order and activity in the lab? How does the requested information get transferred?
- How are orders from the customer received?

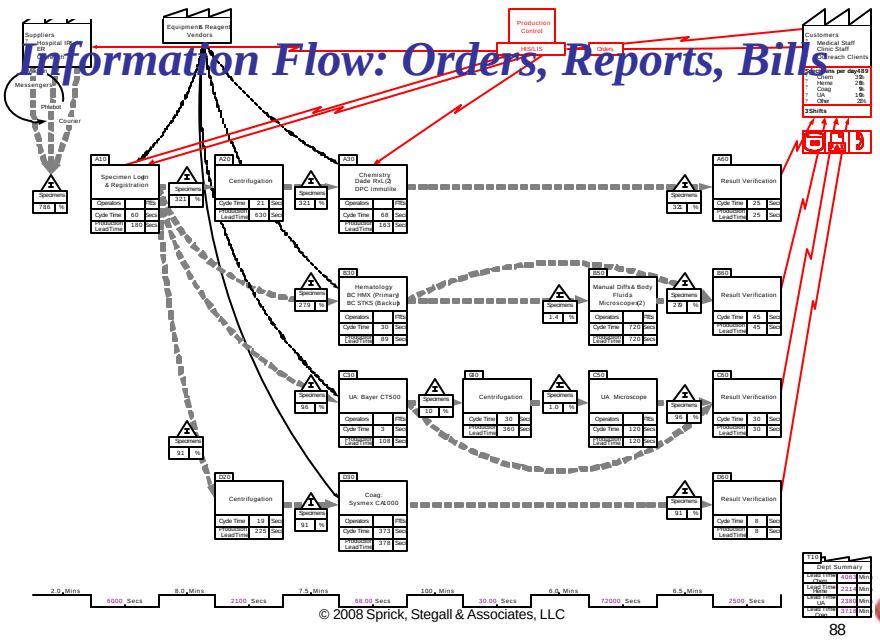
Map layout

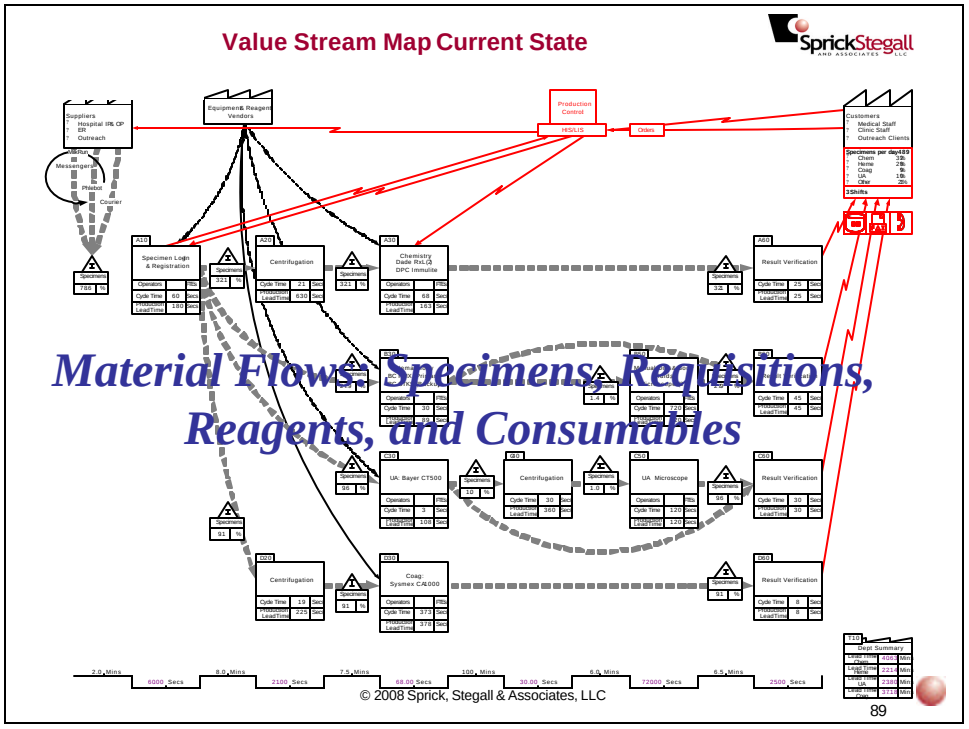


Value Stream Map Current State



Value Stream Map Current State




Value Stream Map Current State
SprickStegall
Material Flow: Specimens, Requisitions, Reagents, and Consumables
© 2008 Sprick, Stegall & Associates, LLC
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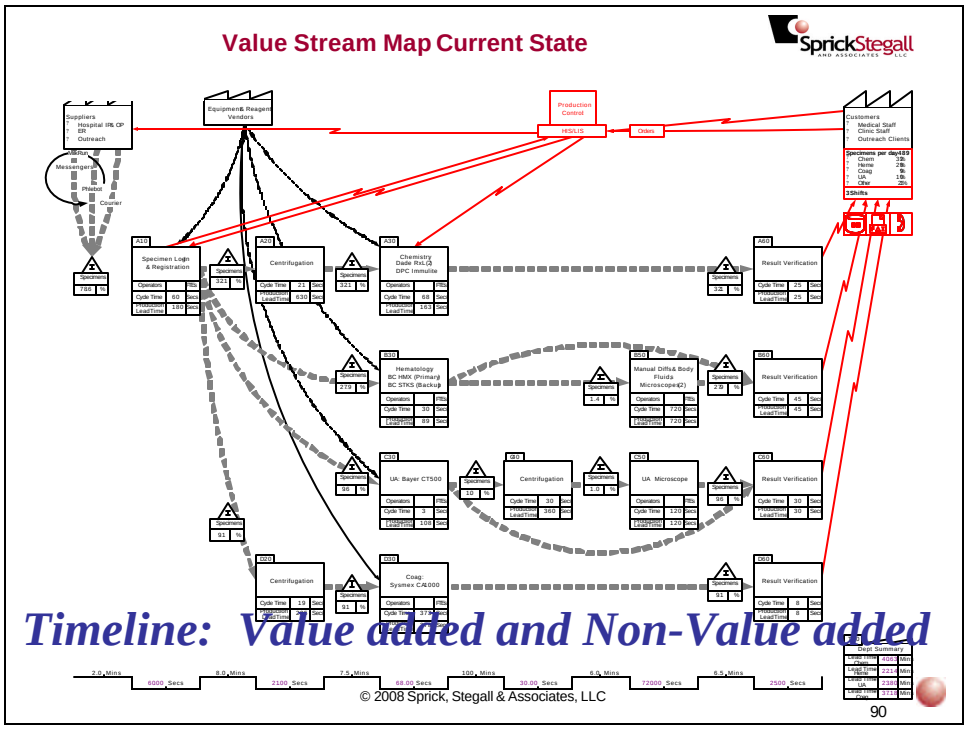
Value Stream Map Current State
SprickStegall
Timeline: Value added and Non-Value added
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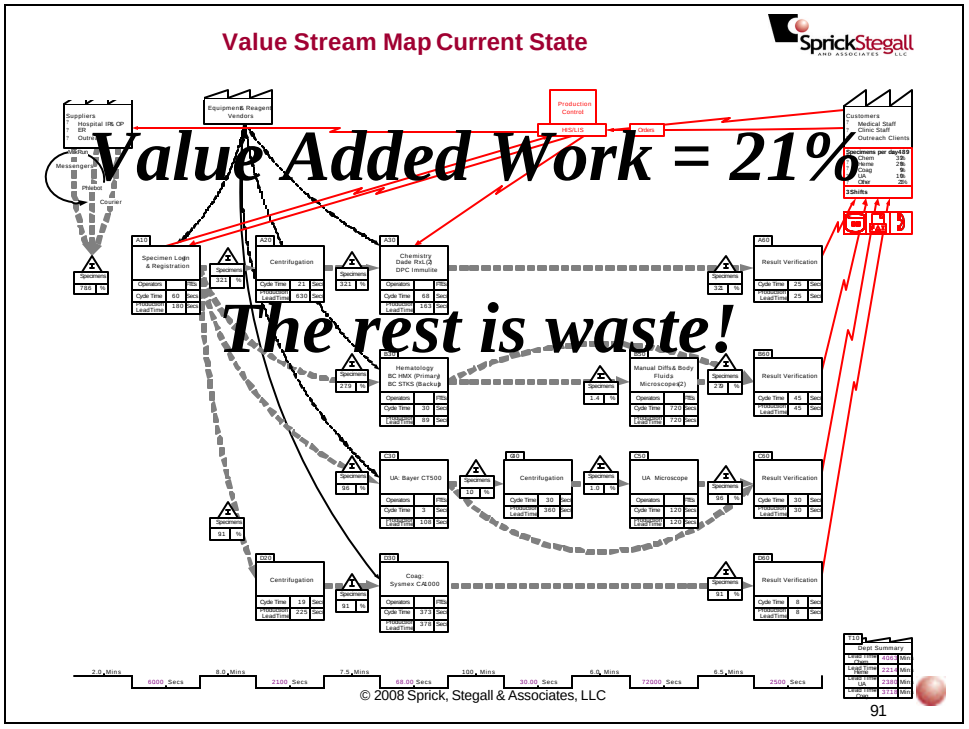
Value Stream Map Current State
SprickStegall
Value Added Work = 21%
The rest is waste!
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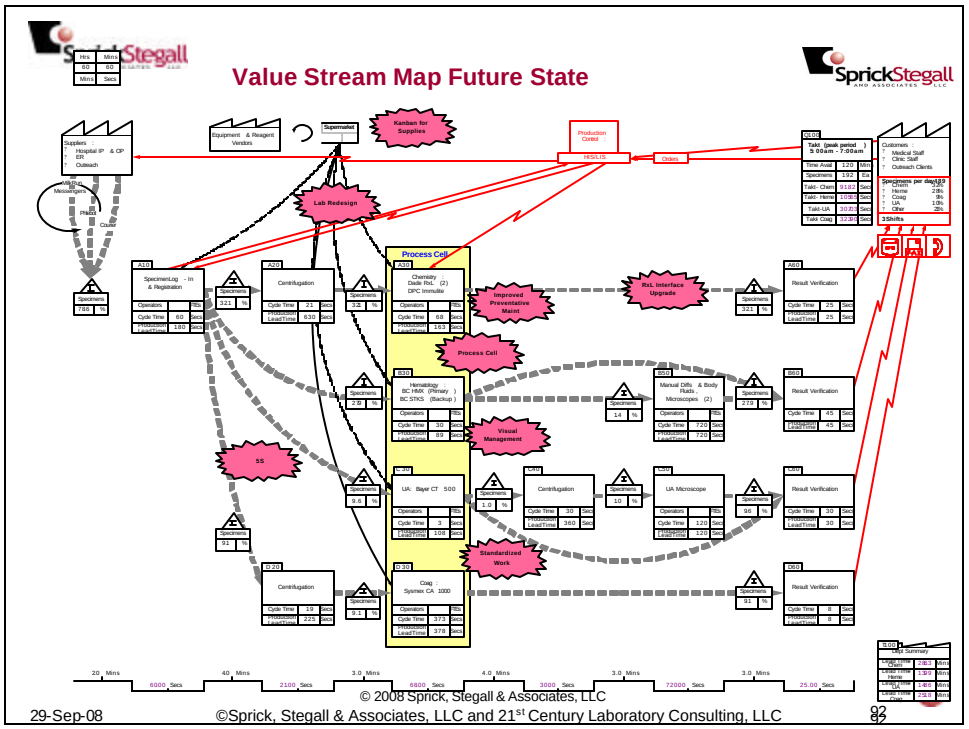
Value Stream Map Future State
SprickStegall
Kanban for Supplies
Lab Redesign
Process Cell
Improved Preventative Maint
RxL Interface Upgrade
Visual Management
5S
Standardized Work
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Icons 101

- **Suppliers and customers**

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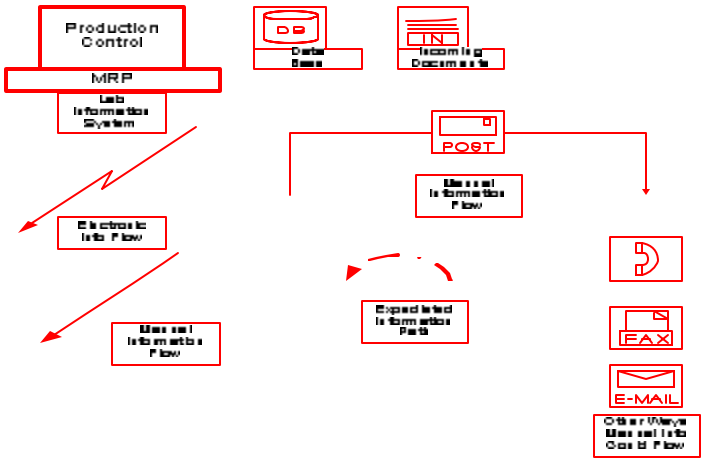
Information Flow Icons



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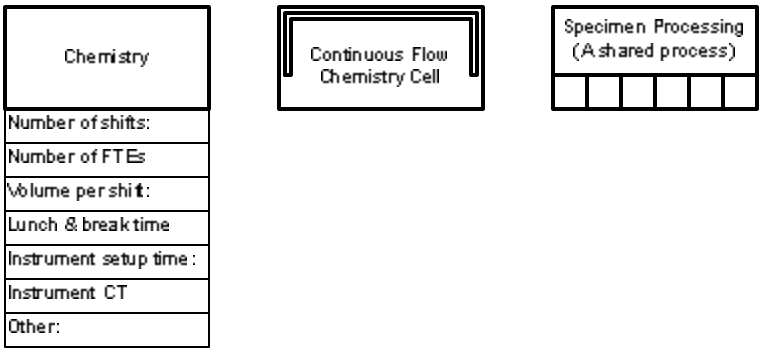
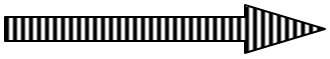
Icons 101

- **Identifying a work process where value is added to the product:**

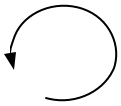


Icons 101

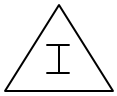


- **Line push connectors (the path of flow)**

- **Finished goods (result reporting in lab lingo)**



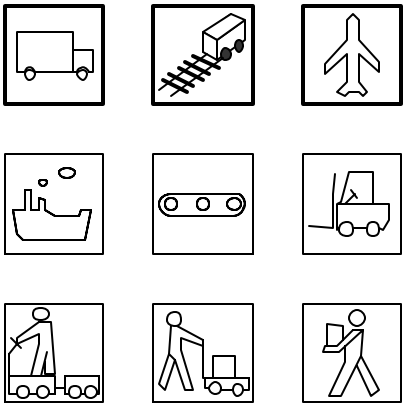
- **Inventory pull system from a supermarket of reagents, supplies and parts**



- **Designation for inventory: specimens, reagents, supplies, consumables, and parts**

Transport Icons

- Designates how materials get moved



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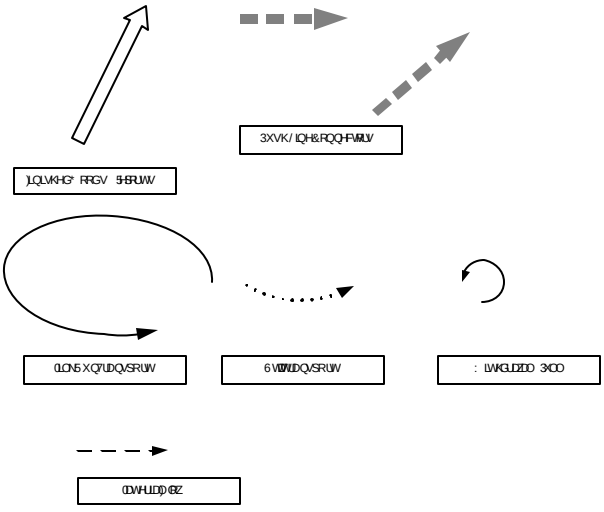
Material Flow Icons



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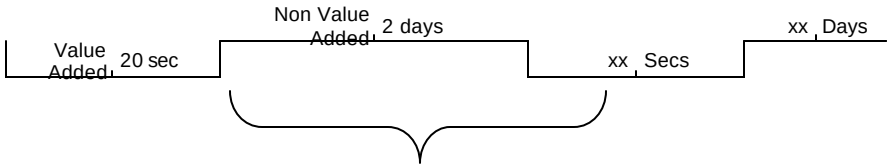
Miscellaneous Icons

- Go and see if there's more work
- Process or performance improvement opportunity



Door to door time measurements

What Are the Value-Added Jobs?

	Stage	Time per Batch
1.	Sorting	2:30 minutes
2.	Registration	15:00 minutes
3.	Order Entry	35:00 minutes
4.	Quality Control	5:00 minutes
5.	Transport to Lab	2:00 minutes

Batch = 15 patients

Total Value-Added Activities = 59:30 minutes

This is the time it should take to register a batch of 15 patients with no waste in the process!

What Are the Non Value-Added Jobs?

	Stage	Time per Batch
1.	Sorting	2:30 minutes
2.	Holding (Storage) ▽	45 minutes
3.	Registration	15 minutes
4.	Holding (Storage) ▽	1:05 hours
5.	Order Entry	35 minutes
6.	Holding (Storage) ▽	1:13 hours
7.	Transport to Lab	2:00 minutes
8.	Quality Control	5:00 minutes

Batch = 15 patients

▽ = Inventory (waste)

Total Non-Value Added Activities = 3:03 hours

These are activities that bring no value to your customers, like waiting, human motion, overproduction, defects, inventory.

What Is the Current Turnaround Time?

- Defined as the average time it takes to complete all steps in a defined process; includes both value-added and non-value-added activities
  - Total Value-Added Activities = 59:30 minutes
  - Total Non-Value Added Activities = 3:03 hours
- Lean terms are "throughput time", "cycle time" or "lead time"
- Seventy-five percent of the Outreach Registration cycle time is classified as waste
  - Most service organizations have 50-80% waste without even knowing it
  - Learning to see waste raises awareness and Lean tools work together to eliminate it from the value-added (important) work

Current Turnaround Time = 4:02:30 hours

(of which 75% brings no value to your customers!)

Value Stream Mapping Exercise

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Overview

- **ABC Health System (ABCHS) is an academic medical center with a dedicated rapid response laboratory serving several ICUs and the ER.**
- **Physician demand for laboratory results is highly variable throughout the day.**
- **At ABCHS, the peak demand in the rapid response lab occurs in the early morning between the hours of 5 A.M. to 7 A.M.**
- **Specimens arrive in the lab by courier or pneumatic tube.**

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Overview (cont.)

- The present laboratory is somewhat disorganized and there are a couple of pallets of un-stocked supplies and reagents on the floor. The early morning is always a bit frantic because of the large number of morning draw s and the 2 hour turnaround expectation of the medical staff doctors. The telephones are ringing off the hook —nurses and ward clerks asking for lab results.
  - Phlebotomy begins at 4:00 AM; team members each draw 20 patient and then return to the lab to drop off specimens and get labels for another 10 to 20 patients. Specimens are sorted in this area by testing de partment and the technologists walk over to get their specimens for testing.
  - Each area in Hematology is organized as a separate workbench and requires lots of operator walking. There is no direct line of s ight to the area were specimens are received.
  - Chemistry instrumentation is located in a common configuration but specimen receipt and the centrifuge are across the room, thus re quiring lots of movement of specimens and staff members to complete the work. Technologists centrifuge their own specimens.

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

- Staffing for the clinical departments is as follows:

Staff	Monday through Friday	Saturday and Sunday
Phlebotomists	5 days 2 evenings 1 nights	3 days 2 evenings 1 nights
Medical Technologists	5 days 3 evenings 2 nights	3 days 2 evenings 2 nights
Managers	1 days 0 evenings 0 nights	1 days (on-call) 0 evenings 0 nights

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Customer Requirements

- 385 specimens per day with the following distribution
  - 35% Hematology
  - 41% Chemistry
  - 12% Urinalysis
  - 12% Coagulation
- 50% of the daily workload arrives during the 2 hour peak period

Work Time

- The rapid response lab operates 24 hour per day 365 days per year
- There are no down periods, except for 30 minutes per day per instrument for maintenance. This is scheduled during the midnight shift.

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Production Processes

- Specimens are all bar coded and orders are immediately downloaded to the LIS from the floors.
- Specimen receipt is verified by scanning the specimens
- Certain specimen types require centrifugation
- The lab performs virtually all of the testing on any of four analyzers
- Results are manually released and are automatically uploaded to the LIS

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Process Information

Specimen Log-in

- Cycle time: 30 seconds
- Observed inventory: 6 - 10 specimens
- Average wait: 2 minutes

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Process Information

Centrifuges, Chem (3)

- Batch Cycle Time: 10 minutes
- Capacity: 40 specimens
- Average batch size: 6 specimens
- Observed inventory: 5 - 6 specimens
- Specimen Cycle Time: 10 min/6 spec = 100 seconds
- Average wait: 2 minutes

Centrifuges, Coag (2)

- Batch Cycle Time: 3 minutes
- Capacity: 40 specimens
- Average batch size: 1 specimens
- Observed inventory: 1 specimens
- Specimen Cycle Time: 3 min/1 spec = 240 seconds
- Average wait: 2 minutes

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Process Information

Chemistry Analyzer (1)

- Cycle time: 68 seconds
- Process lead time: 163 sec
- Observed inventory: 4 specimens
- Average wait: 3 minutes

Hematology Analyzer (1)

- Cycle time: 45 seconds
- Process lead time: 89 sec
- Observed inventory: 4 specimens
- Average wait: 3 minutes

Urinalysis Analyzer (1)

- Cycle time: 30 seconds
- Process lead time: 108 sec
- Observed inventory: 1 specimens
- Average wait: 5 minutes

Coagulation Analyzer (1)

- Cycle time: 373 seconds
- Process lead time: 378 sec
- Observed inventory: 1 specimens
- Average wait: 5 minutes

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Result Verification

- Cycle time: 30 seconds
- Review results--electronic inventory: 12 specimens
- Average wait: 2 minutes

Value Stream Mapping Exercise: Case Study - ABC Health System (Current State)

Assignment 1:

- Develop the current state value stream map showing supplies, customers, all processes.
- Determine value added and non-value added activities.
- Determine "door-to-door" turn around time
- Indicate push or pull flows for specimens and supplies
- Draw in information flows

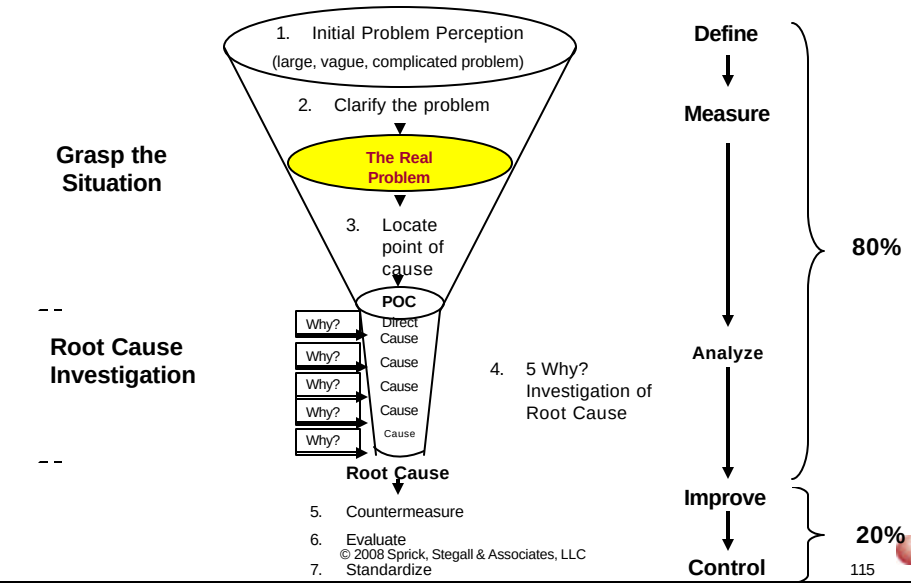
Assignment 2:

- List the types of waste present
- Brainstorm the Future State and pencil in the Kaizen Events on the Current State map

Tool #3- Problem Solving

- Form Problem Solving Teams.
  - Work on things most important to the operators first. If they aren't on your side, you won't accomplish anything.
- Define the problem.
- Ask "Why?" five times. Get to the root cause before taking action.
- Containment actions– things that can be done immediately to resolve a problem
- Brainstorm for ideas– everyone on the team should bounce around their ideas to fix the problem.
- Set up an Action Plan detailing who does what, by what date.

Toyota: One Problem Solving Process for Everyone



Comparison of Toyota Problem Solving and DMAIC

Toyota Problem Solving	Six Sigma
Go and See	Collect Data
Management by Fact	Validated Data
Visual Data Displays	Statistical Analysis
Shop Floor Driven	Expert Driven
Daily Kaizen	Project Focus
Value Stream Focus	Process Focus
Bias for Action (learn by doing)	Bias for Analysis (predict and control)

Comparison of Toyota Problem Solving and Lean Tools

Toyota Problem Solving	Lean Tools
Total Systems Approach	Tools for Pull and Flow
People Centered	Technically Driven
Management Philosophy	Technical Staff Projects
Shop Floor Driven	Expert Driven
Daily Kaizen	Project Focus
Value Stream Management	Value Stream Mapping
Evolutionary	Quick Hits

"5 Why" Investigation

	Level of Problem	Level of Countermeasure
	There is a puddle on the floor.	Clean up the puddle.
Why?	Because the machine is leaking.	Fix the machine.
Why?	Because the gasket has deteriorated.	Replace the gasket.
Why?	Because we bought inferior gaskets.	Change gasket specifications.
Why?	Because we got a good price.	Change purchasing policies.
Why?	Because the purchasing agent gets evaluated on short-term cost savings	Change the evaluation policy for purchasing agents.

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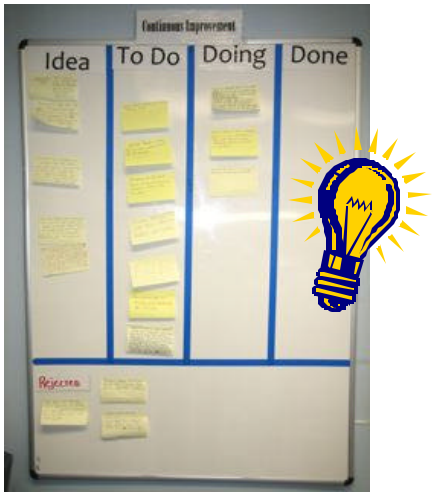
Hey! I've Got a Better Idea!

Hey! I've Got a Better Idea!			
Your suggestion:			
Evaluation by the Process Improvement Committee:			
As safe or safer?	Yes	No	Comments:
Better Quality?	Yes	No	Comments:
Better Time?	Yes	No	Comments:
Lower Cost?	Yes	No	Comments:
Better Morale?	Yes	No	Comments:
A No answer to any question may not be a Better Idea.			

The Idea Board

- **Step 1: employees write ideas on Post-Its**
- **Step 2: ideas get reviewed and advanced or rejected**
- **Step 3: ideas move from "To Do" to "Doing" and notes on back document plans**
- **Step 4: Once idea is implemented, note is moved to "Done" column**
- **Step 5: status of ideas are discussed in weekly staff meetings**
- **Step 6: rewards for reaching implemented status may keep motivation high**



Idea board implemented by Lean Team

Problem Solving Worksheet

SprickStegall

1. Identify the Team

Department Name

Leader

2. Define the Problem

Description

Date Discovered

Sketch:

3. Containment Actions:

4. Chart Actual Errors and Goal:

Problem Solving Worksheet

SprickStegall

5. Brainstorm for Ideas:

6. Primary Contributors:

7. Set Action Plans: Who By When Results/Comments

a.

b.

c.

d.

e.

8. Follow Up:

How Check

When Check

Next Meeting: Time: Place

Tool #4- 5S and Visual Management

- 5S's clean up your environment:
  - Sort: stuff we use, stuff we might use, stuff we never use.
  - Stabilize: a place for everything and everything in its place.
  - Shine: clean everything.
  - Standardize: everybody does it right the first time, every time.
  - Sustain: culture, philosophy, discipline.

5S and Visual Management

- Assign 5S responsibilities.
  - 5S zones and end-of-shift duties (Posted)
    - Red tag everything that is to be removed from the area
    - Never label anything that does not belong in the area
  - Work on things that are most important to the laboratorians.
    - What do they need to get started?
    - Are all the tools in place when they need them?

5S and Visual Management

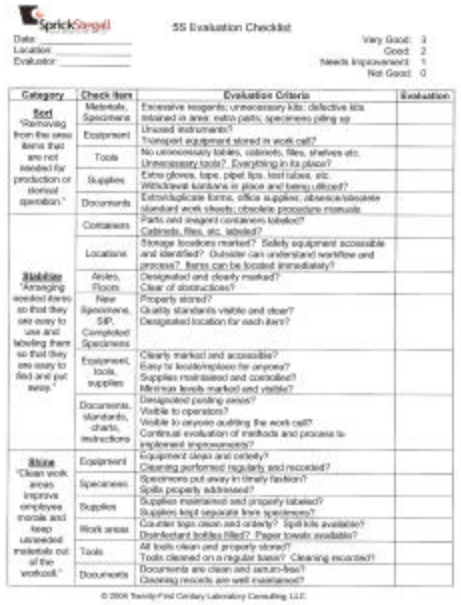
- Integrate 5S duties into the regular work pattern.
  - Remember, 5S is not a goal, it is a productivity tool
- Audit performance on a regular basis.
  - Grade all areas on 5S perfection
  - Have sections audit each other. A little competition can be healthy.
  - Reward the winners.
  - Make sure the losers know where they need to improve.

5S Assignment Sheet

Week of: _____ Workstation: _____

Name	M	Tu	W	Th	F	Sa	Su

5S Audit Checklist



5S Evaluation Checklist

Date: _____
Location: _____
Evaluator: _____

Very Good: 3
Good: 2
Needs Improvement: 1
Not Good: 0

Category	Check Item	Evaluation Criteria	Evaluation
Sort "Removing from the area items that are not needed for production or normal operation."	Materials, Specimens	Excessive reagents; unnecessary kits; defective kits retained in area; extra parts; specimens piling up	
	Equipment	Unused instruments? Transport equipment stored in work cell?	
	Tools	No unnecessary tables, cabinets, files, shelves etc. Unnecessary tools? Everything in its place?	
	Supplies	Extra gloves, tape, pipet tips, test tubes, etc. Withdrawal fixtures in place and being utilized?	
	Documents	Extra/duplicate forms, office supplies; absence/obsolete standard work sheets; obsolete procedure manuals	
Stabilize "Arranging needed items so that they are easy to use and labeling them so that they are easy to find and put away."	Containers	Parts and reagent containers labeled? Cabinets, files, etc. labeled?	
	Locations	Storage locations marked? Safety equipment accessible and identified? Outsider can understand workflow and process? Items can be located immediately?	
	Aisles, Floors	Designated and clearly marked? Clear of obstructions?	
	New Specimens, SIP, Completed Specimens	Properly stored? Quality standards visible and clear? Designated location for each item?	
	Equipment, tools, supplies	Clearly marked and accessible? Easy to locate/replace for anyone? Supplies maintained and controlled? Minimum levels marked and visible?	
	Documents, standards, charts, instructions	Designated posting areas? Visible to operators? Visible to anyone outside the work cell? Continual evaluation of methods and process to implement improvements?	
Shine "Clean work areas, improve employee morale and keep unneeded materials out of the workcell."	Equipment	Equipment clean and orderly? Cleaning performed regularly and recorded?	
	Specimens	Specimens put away in timely fashion? Spills properly addressed?	
	Supplies	Supplies maintained and properly labeled? Supplies kept separate from specimens?	
	Work areas	Counter tops clean and orderly? Spill kits available? Disinfectant bottles filled? Paper towels available?	
	Tools	All tools clean and properly stored? Tools cleaned on a regular basis? Cleaning recorded?	
	Documents	Documents are clean and serum-free? Cleaning records are well maintained?	

Tool #5 - Standardized Work

- **Standardized Work is:**
  - **A standardized method of achieving efficient result production without waste, based on human motion.**
  - **It provides the basis for Continuous Improvement.**
  - **It makes problem solving easier by limiting complexity and variance.**

What is Standardized Work?

- Detailed and documented system in which each worker develops and follows a repeatable sequence of tasks within a work assignment
- Work sequence represents the best practices to follow
  - Documented and displayed at each workstation
  - Employees are taught these practices
  - Adherence to work sequence is audited
- The experts (i.e. the workers) determine the work sequence and timing of events
- Once the sequence of job elements is effectively organized, it is repeated over and over by the workers

What is Standardized Work?

- Aim is to reduce the variation introduced by the operator to
  - Eliminate waste, and
  - Achieve high productivity
- Baseline for a continuous improvement philosophy that involves the employees

Three Fundamental Principles

- Principle #1: Improve Quality
  - Design a process where the variation introduced by the worker is minimized
  - Generate and maintain a baseline
  - When problems arise, audit back to the standard
  - Either return to the baseline or improve the process

Three Fundamental Principles

- Principle #2: Eliminate Waste
  - Focus on reducing unnecessary movement of the workers (i.e. waste)
  - Make steps to eliminate waste once it is identified
  - Charge workers with the responsibility to identify waste and continually improve their processes

Three Fundamental Principles

- **Principle #3: Involve Employees**
  - **Encourage workers to become involved, rather than using management engineers to set work practices**
  - **View standardized work as the vehicle through which employees can be involved and voice his/her opinion on how to do the work**
  - **Note: workers must be willing to change their behavior to benefit from standardized work**

Standardized Work Requires Change

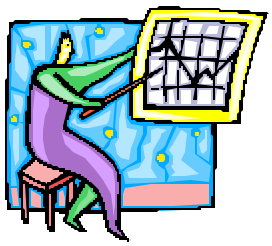
To Turn Principles → **Into Benefits**

Requires

Behavior Change

And

Discipline



Typical Problems

- Labor imbalances
- Poorly defined work sequence
- Poor workplace organization
- Inadequate tools
- Difficult work methods
- Little or no support
- Loose or no specs

- Irregular work flow
- Poorly defined responsibilities
- Incapable processes
- Cycle time/Takt time unclear
- Variability in the workplace
- Poor communication
- Lack of core skills

Why is Standardization Important?

- Maintains the level of QUALITY
- Stabilizes the working conditions
- Increases the level of SAFETY
- Allows clear judgment of normal from abnormal conditions
- COST REDUCTION
- Stability of operating time (takt time)
- ELIMINATE WASTE
- Improve MORALE
- Increase PRODUCTIVITY
- Provides the basis for continuous improvement

Standardized Work: Simple Tools

1. **Job Analysis Data Sheet**
   - Identify the steps that must be accomplished to complete work processes one time.
   - What are the time elements involved in each step of the process? How long does it take to perform each work element?
   - Can some elements be combined to save time?
   - Can some of the work elements be combined to level staff member workloads?
   - What is the bottle-neck process in the work cell? (Any log jams?)
2. Standardized Worksheet
3. Stack Chart (line balance)

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1. Job Analysis Data Sheet

Job Description: Making Pen Holders	Operator Name:	Shift:	Date:	Analyst:			
	Repetition with Time in Seconds						
Work Element	1	2	3	4	5	6	7
1. Cut 1, 2, & 3	27.5						
2. Cut 4, 5, & 6	62.9						
3. Cut 7 & 8; Fold 1 through 8.	139.4						
4. Glue and Assemble Pen Holder	224.7						
5. Stuff Assembled Holder with Tissue paper, Candy and Pen.	233.2						
Total For Each cycle	233.2						

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1. Job Analysis Data Sheet (cont.)

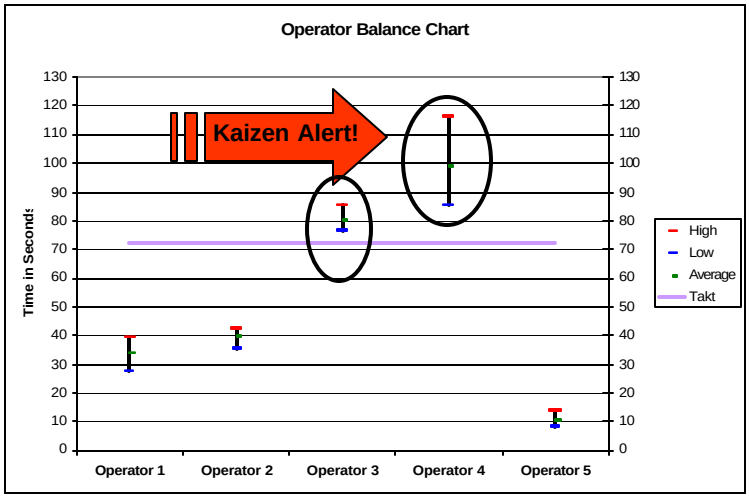
Job Description: Making Pen Holders	Operator Name:	Shift:	Date:	Analyst:			
	Repetition with Time in Seconds						
Work Element	1	2	3	4	5	6	7
1. Cut 1, 2, & 3	27.5 / 27.5						
2. Cut 4, 5, & 6	35.4 / 62.9						
3. Cut 7 & 8; Fold 1 through 8.	76.5 / 139.4						
4. Glue and Assemble Pen Holder	85.3 / 224.7						
5. Stuff Assembled Holder with Tissue paper, Candy and Pen.	8.5 / 223.2						
Total For Each cycle	233.2						

Then calculate individual work element time by subtracting

1. Job Analysis Data Sheet (cont.)

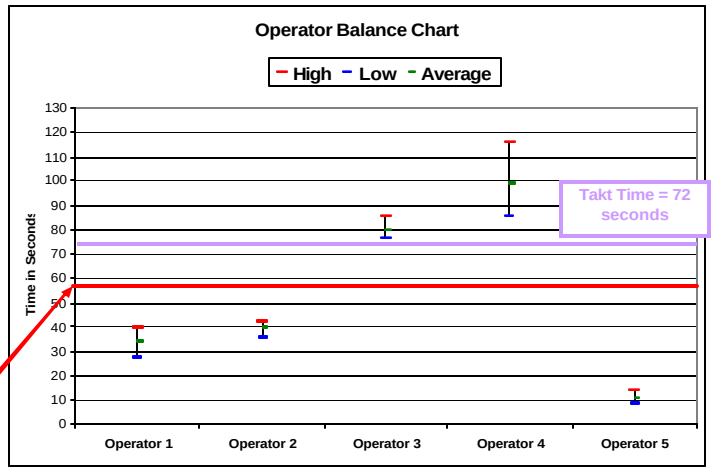
- Work elements should be developed by the operators performing the work.
  - Each work element has to be measured from fixed point to fixed point—a defined beginning and end point.
  - The operators must agree what the work elements are -- standardization.
  - At least ten measurements of each work element should timed.
  - An "Operator Balance Chart" with cycle time variation should be developed from this information.
    - Pay particular attention to the minimum and maximum times.
    - Do not use averages.
    - Variation between the minimum and maximum should be the area of focus for standardized work waste reduction—kaizen.

1. Job Analysis Data Sheets (cont.)



1. Job Analysis Data Sheets (cont.)

Plan production time for each value-added operator at 80% of Takt Time



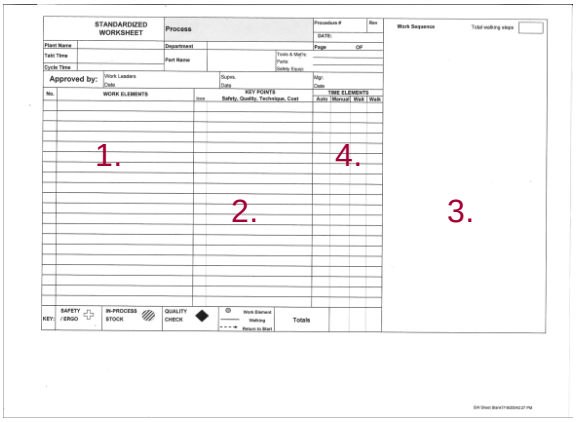
Simple Tools

1. Job Analysis Data Sheet
2. Standardized Worksheet
   - What are the steps needed to complete this process? (Work sequence)
   - What are the safety and quality concerns with this process?
   - How much work can be performed at one time in this process?
3. Stack Chart (line balance)

Standardized Work Tools

The Standardized Worksheet is organized into four sections:

1. Work Elements
2. Key points
3. Work sequence
4. Time information



SprickStegall	Standardized Worksheet	Process:	Date:	Work Area Layout
Lab Name		Department		Page ____ of ____
Takt Time		Test Name		
Cycle Time		Test #		
APPROVED BY:	Team leaders Date	Supervisor Date	Mgr. Date	

No.	WORK ELEMENTS	KEY POINTS Icon	Safety, Quality, Techniques, Cost	TIME ELEMENTS Auto	Manual	Wait	Walk
			Totals				

Tells how to do the job in simple steps.

Explains important points about each step.

Time Information

Work Sequence
Diagrams
Sketches
Photos

Icons: Safety + | In Process Stock ○ | Quality Check ◆ | Work Element **F**

Walking ——— | Return to Start - - - →

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SprickStegall

Standardized Worksheet

- **Must contain three elements:**
  - **The work sequence**
  - **Standard work in process**
  - **Takt time = $\frac{\text{Time Available}}{\text{Customer requirements}}$**
- **Standardized work is centered around human movement**
  - **Work is performed the same way every time, by every member of the team.**

Basic Work Elements

- An element is a fixed amount of work.
- It should have a defined start and stop.
- An element is something you can teach
  - Keep it short if possible; not too broad, not too specific
- As you complete an element, you advance the job in some way

Basic Work Elements

- Your ability to describe a job in terms of work elements is an important skill for creating Standardized Worksheets.
  - Elements are used to describe the steps to operate a machine, assemble a test, or set up a test.
  - Their purpose is to make instruction clear and easy to understand.
  - Work elements usually take the form of a verb/object.

Examples of Work Elements

- **Good Examples:**
  - **Pipette 100 µL of serum.**
  - **Add 300 µL of PBS.**
  - **Incubate at 37° C for 30 min.**
  - **Transfer 20 µL of diluted specimen to the reaction well.**
  - **Examine at 40x for the presence of cells.**
- **Poor Examples:**
  - **Dilute all specimens (too general).**
  - **Assemble all test materials (too broad).**
  - **Hold the tissue block and trim it with a razor blade until the desired shape and size is obtained (multiple steps).**
  - **Arrange 12 test tubes in a rack (too detailed).**

Key Points

- **Key points involve such factors as special motions, special information, feel, knowledge of risk or maybe the ability to distinguish unusual sounds.**
- **One of the following conditions must be met:**
  - **Safety (injury prevention)**
  - **Quality (defect detection)**
  - **Technique (ease of work, look and feel)**
  - **Cost (material usage)**
- **Examples:**
  - **Inspection points where defects typically occur.**
  - **How to hold a pipette to prevent wrist injuries.**
  - **How to trim tissue specimens without injuring yourself.**
  - **How to enter information into the instrument.**
  - **What chemicals should not be used in the same reaction well.**

Work Elements vs. Key Points

Work Elements	Key Points
Logical segments of work	Complete description of work
Tells "what" to do	Tells "how" to do it
Not overly descriptive	Conveys special information - Safety - Quality - Technique - Cost

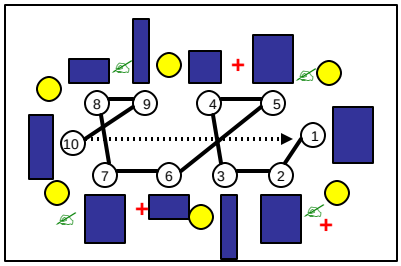
Identifying Work Elements and Key Points is an important skill for preparing Standardized Worksheets.

Drawing the Work Sequence

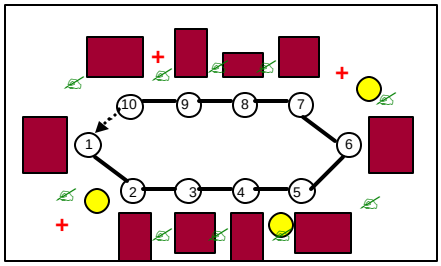
- Work area layout to approximate scale
  - Instruments, tables, computers, pipettes, etc.
  - Scope of worker's job only.
- Number and circle work elements (2)
- Connect work elements with a solid line
- Return to start with a dashed arrow
- Enter SWIP (number if more than one)
- Quality Check (on drawing & key points)
- Safety Check + (on drawing & key points)

Work Sequence

Poor



Good



- **Work Sequence refers to the series of steps in a process that is fastest, safest, most efficient, and of acceptable quality.**
- **When the work sequence is followed, the cycle time will be constant, no steps will be forgotten, and the chance of equipment damage or other major problems will be minimized.**

Standardized Work Chart Displays

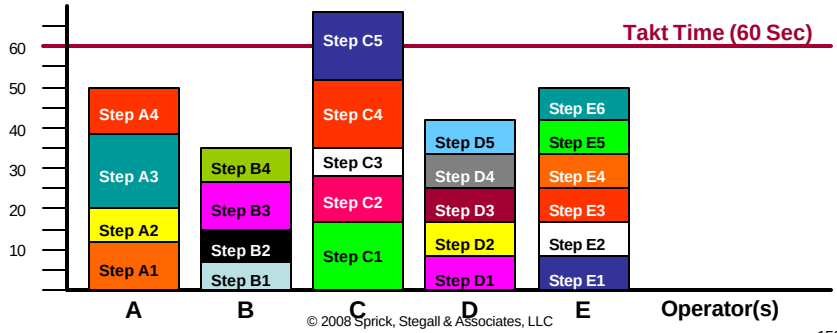
These document displays are available from MarketLab, Inc.

Simple Tools—
Stack Chart for Line Balancing

1. Job Analysis Data Sheet
2. Standardized Worksheet
3. **Stack Chart (line balance)**
   - **How are the machines and staff members in the workcell being utilized?**
   - **Can work from one machine, work process, person or area be transferred to/from another machine, work function, person or area?**
   - **Do we need to add/subtract another machine, work process step or staff member?**

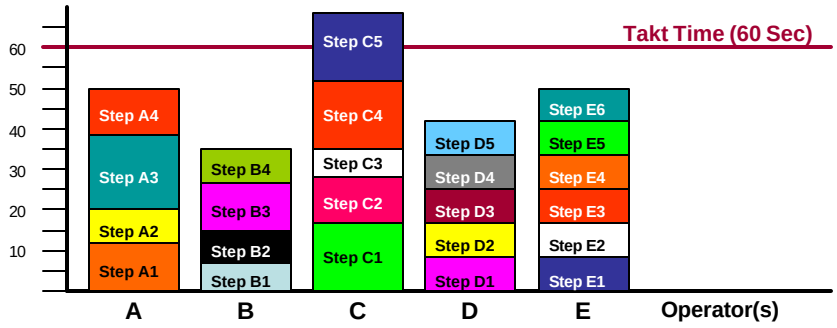
Stack Chart to Determine Line Balance

- **If Takt Time and Planned Cycle Time are not the same, an imbalance exists in the operating system.**
- **If Planned Cycle Time is less than or equal to Takt Time, production will satisfy customer demand.**
- **If Planned Cycle Time is greater than Takt Time, production cannot satisfy customer demand.**



Kaizen to Balance the Workload

- Operator B and D have time to spare
- Operator C is not meeting customer demand
- Solution: Kaizen the C work cell as shown on the next slide.



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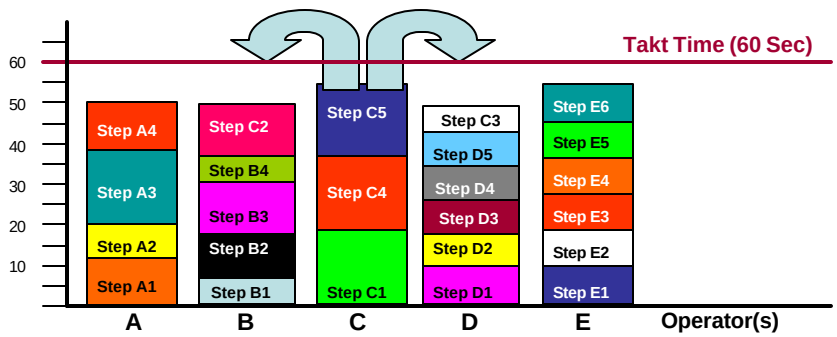
Balanced Production

- Process C2 is moved to the B work cell while process C3 is moved to the D work cell.
- Everybody meets takt time.



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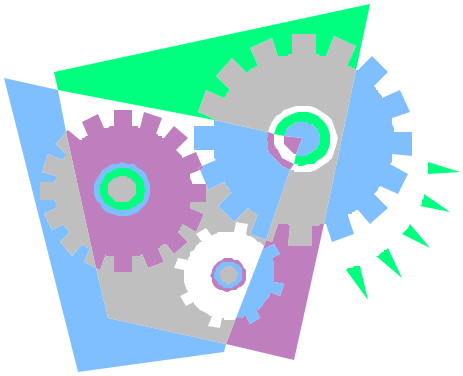
Benefits of Standardized Work

1. Reduces the variation of human intervention
2. Improves the level of safety in the workplace
3. Stabilizes working conditions, reduces stress among the workers and encourages harmony

Benefits of Standardized Work, cont.

4. Reduces rework
5. Distributes work fairly among employees

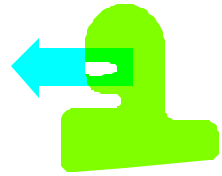


Benefits of Standardized Work, cont.

6. **Allows real time operational conditions to be visible to management**
   - **Any "behind schedule" conditions are easier to see and**
   - **Corrective action can be taken faster**

Benefits of Standardized Work, cont.

7. **Improves communication**
8. **Trains new employees in a standard manner**
   - **Worksheet provides a documented baseline from which to train**
   - **Teaches the correct work sequence and eliminates variability among workers**
   - **Introduces principles of standardized work early on**
   - **Identifies skill deficiencies among existing staff and improves them through training**



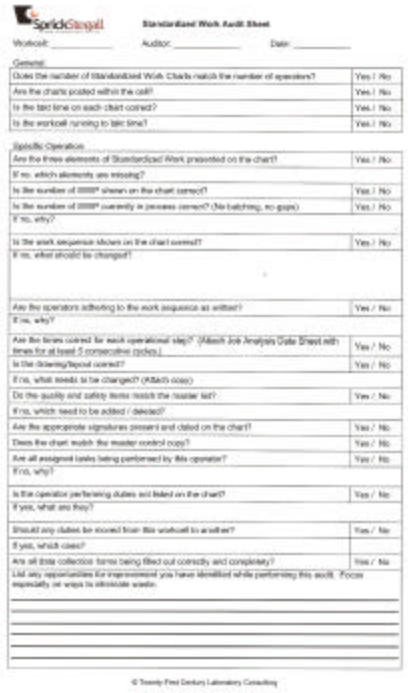
Benefits of Standardized Work, cont.

9. Promotes continuous improvement philosophy
   - When work is standardized, all workers know the current work sequence
   - This understanding allows workers to suggest improvements, i.e. continuous improvement
   - The process can be improved and then it becomes the new baseline of standardized work
   - Remember that continuous improvement is unmanageable without standardization!
10. Improves productivity while decreasing worker demand

Maintaining Standardized Work

1. Establish a formal process to enforce standardized work
2. Use an audit form to document conformance
3. Ask: "How well does the worker conform to it?"
4. Turn audit into a training tool for employees
5. Conduct audits by supervisor, not colleague

Standardized Work Audit Form



Standardized Work Audit Sheet

Workcell: _____ Auditor: _____ Date: _____

General:

Does the number of Standardized Work Charts match the number of operators?	Yes / No
Are the charts posted within the cell?	Yes / No
Is the takt time on each chart correct?	Yes / No
Is the workcell running to takt time?	Yes / No

Specific Operation:

Are the three elements of Standardized Work presented on the chart?	Yes / No
If no, which elements are missing?	
Is the number of ????? shown on the chart correct?	Yes / No
Is the number of ????? currently in process correct? (No batching, no gaps)	Yes / No
If no, why?	
Is the work sequence shown on the chart correct?	Yes / No
If no, what should be changed?	
Are the operators adhering to the work sequence as written?	Yes / No
If no, why?	
Are the times correct for each operational step? (Attach Job Analysis Data Sheet with times for at least 5 consecutive cycles.)	Yes / No
Is the Obeing/Tapout correct?	Yes / No
If no, what needs to be changed? (Attach copy)	
Do the quality and safety items match the master list?	Yes / No
If no, which need to be added / deleted?	
Are the appropriate signatures present and dated on the chart?	Yes / No
Does the chart match the master control copy?	Yes / No
Are all assigned tasks being performed by this operator?	Yes / No
If no, why?	
Is the operator performing duties not listed on the chart?	Yes / No
If yes, what are they?	
Should any duties be moved from this workcell to another?	Yes / No
If yes, which ones?	
Are all data collection forms being filled out correctly and completely?	Yes / No

List any opportunities for improvement you have identified while performing this audt. Focus especially on ways to eliminate waste.

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Maintaining Standardized Work, cont.

6. **At least once per month, survey the workers to see if there are problems.**
   - **Are the objectives clear?**
   - **Is there adequate concentration on the objectives?**
   - **Are there too many distractions to allow for the objectives to be completed?**
   - **Is management giving clear and immediate feedback on progress toward the objective?**
   - **Are you being sufficiently challenged with the task at hand?**

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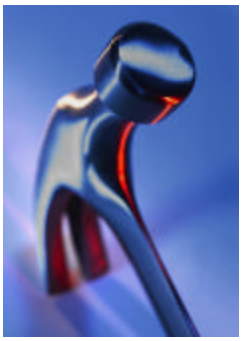
Old Paradigm

If managers say, "I don't care how you do it, just get the job done!"

then

people do whatever they can to get results . . .

. . . no matter if this yields inconsistent results!!!



"If all you have is a hammer, then everything looks like a nail."

-- Bernard Baruch

New Paradigm

If managers say, "Everyone does the job the same way each time. No exceptions."

then

people, with discipline, begin to change their behavior, and . . .

. . . see that consistent processes yield consistent results!

The Best Way to do Kaizen Events

What is a Kaizen Event?

- A Team activity that rapidly uses Lean methods and tools to eliminate waste in laboratory operational processes
- A kaizen event is organized in three phases:
  - Phase I: Team formation, training, area selection, and preparation—5 Steps
  - Phase II: Assessment, action planning and implementing—3 Steps
  - Phase III: Presenting, celebrating and follow up monitoring—3 Steps
- Examples of kaizen events:
  - 5S a department
  - Redesign a work cell
  - Developing and implementing standardize work routines
  - Move from batch testing to continuous flow testing
  - Setting up an inventory kanban system

What's the Purpose of Kaizen?

- Kaizen process improvement activities focus on a sequence of operational processes with the aim of eliminating waste:
  1. Overproduction
  2. Transportation
  3. Inventory
  4. Processing
  5. Waiting
  6. Motion
  7. Defects
  8. Not using the ability and intellect of your staff
- Waste adds cost and/or time but does not add value to your product.
- Kaizen is accomplished through small continuous improvement teams.

Phase I: Team Support Structure—
Key Roles for a Successful Kaizen Event

External Facilitator and/or Internal Lean Team

- Purpose: They help you become skilled at running kaizen events
- Their Goals:
  1. That you learn to conduct kaizen events on your own after a few experiences, and
  2. That you can begin to train others in your organization
- Their duties:
  - Work with all key players in planning and follow up phases,
  - Train team,
  - Support team leaders,
  - Ensures effective communication, and
  - Serves as the link between top management and the team

Phase I: Team Support Structure:
Key Roles for a Successful Kaizen Event (cont.)

Upper Management: (Administrators, Medical Directors and Technical Directors)

- **Purpose: They lend full support toward a Lean culture**
- **Goals:**
  1. **They make it clear that Lean will not endanger anyone's job,**
  2. **They become the source of strength as managers and staff progress through the change process, and**
  3. **They attend presentations of Lean kaizen events in order to provide required support and resources while ensuring sustained results.**
- **Duties:**
  - **Decides which kaizen events are needed/desired.**
  - **Chooses facilitators.**
  - **Select Lean team members.**

Phase I: Area Selection

Step 1 – Select a Department or Function

- **Choose area that will have an impact; when first starting out, choose an area that does not have too many difficult problems to solve**
- **Each event will improve the experience level of the team and build the necessary confidence for more complex areas and problems**
- **Use a selection matrix to compare areas**
- **Important to consider:**
  - **Area deluged with "Work In Process", e.g., technical areas that batch**
  - **Area where activities occur all over, e.g., lab supplies**
  - **Area with significant bottleneck, e.g., specimen processing**
  - **Area where everything is a mess**

Phase I: Area Selection (cont.)

Step 2: Select a Value Stream or Operational Process for Improvement

- Define the value stream or processes clearly; talk to the workers to understand the problems
- Preparation depends on the tools that you will use to eliminate the waste
- One good place to start – wasted motion
  - What gets in the way of workers?
  - When do workers move?
  - How often do they look for tools?
  - What is value-added? What isn't?
- No problem solving here! All high-level rapid plant assessment!

Phase I: Structuring & Training the Team

Step 3: Select the Team Leader

- Their roles:
  - Leads team conducting event
  - Helps prepare, creates schedule, gathers needed materials/tools
  - Helps remove obstacles
  - Helps with documentation and reporting
  - Keeps team on target
  - Supports problem solving among the team members
- Leader should not be from the area of the kaizen event
- Leader should be trained to use the Lean tool set and should be knowledgeable about change management

Phase I: Structuring & Training the Team (cont.)

Step 4: Select the Team Members

- These are the people who actually conduct the kaizen event
- Six but no more than twelve people; two from the area; the manager or supervisor of the area--try to get your brightest and best people
- Train team members on change management and the use of the Lean tool set
- Members gather ideas from other workers in the area
- Key role: They must support the potential of the kaizen event
- Taboo Phrases:
  - "It won't work."
  - "This is good enough."
  - "We're already doing fine. We don't need to change."
  - "I'm too busy to do it."
  - "It can't be done."

Phase I: Team, Staff, and Area Preparation

Step 5: Prepare the Area

- Inform the staff members working in the area or department why their area was selected for process improvement
- Create a charter
- Train the Lean team how to conduct a Lean assessment—Rapid Plan Assessments, spaghetti diagrams, tube travel diagrams, cycle time measurements, value stream mapping, kaizen eyes, etc.
- Schedule the event starting with assessment first, followed by action plan development, and then implementation. (3 to 5 days) (Rapid process improvement.)
- Ensure effective communication throughout: use a process improvement board, talk with staff members, send emails, develop and post charts, graphs, and/or perform post Kaizen audits.

Team Charter Form

Team Charter

Name of Team: _____

Objective: _____

_____

Sponsor: _____

Leader: _____

Coach: _____

Team Members: _____

_____

Deliverables: _____

_____

_____

- Metrics: _____
- Timeline: _____
- Updates: _____

_____

Boundary Conditions: _____

_____

_____

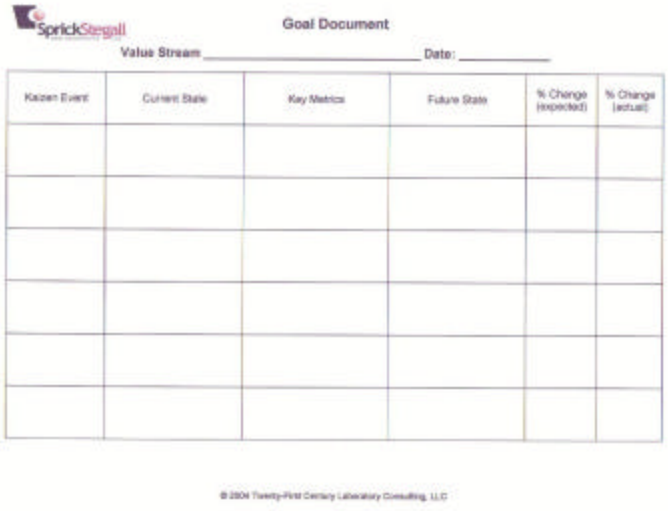
Time Constraints: _____

Sponsor: A manager level leader who is overseeing the activity of the team. The Sponsor is usually not a member of the team, but provides support for the team to succeed, while also providing accountability. Sponsor meets weekly with Leader challenging thinking and thoroughness and providing needed support. Sponsor is accountable to the Lean Steering Committee for the success of the team.

Leader: Leads the team and is personally invested in seeing the team succeed. The Leader has the accountability to facilitate the process through to completion. Accountable to Sponsor for continued progress and success.

Coach: Provides educational and directional support to teams upon request of the Leader. Coordinates Lean efforts throughout the site.

Goal Document Form

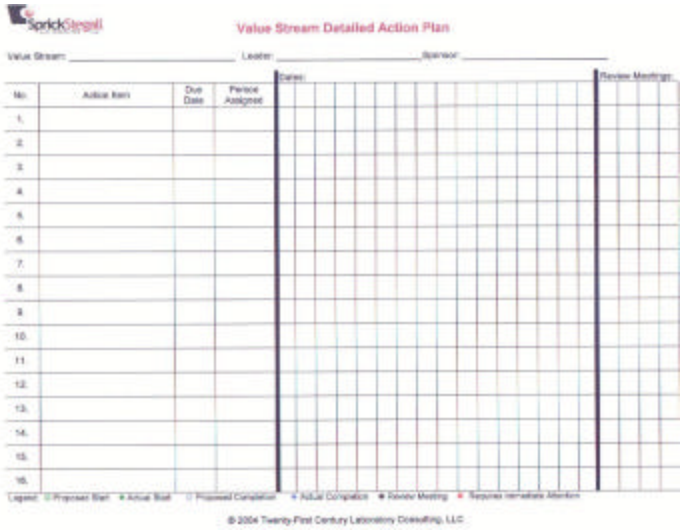


Goal Document

Value Stream _____ Date: _____

Kaizen Event	Current State	Key Metrics	Future State	% Change (expected)	% Change (actual)

A Detailed Action Plan Form



Phase II: Planning (80%) and Implementing (20%)

- **Step 1: Assessment—Understand the Current Situation—Study Thoroughly and Then Implement Rapidly:**
  - **Observe the selected area and gather data – R.L. A.**
  - **Map the process**
    - **Value Stream Mapping**
    - **Tube Travel Diagram**
    - **Spaghetti Diagram**
    - **Take pictures of waste**
  - **Do time studies of all operations—cycle times**
  - **Count WIP; count steps**
  - **Measure early and measure often!!!**
  - **Show metrics on Goal Document**

TOOLS YOU LEARNED ABOUT TODAY!

Phase II: Planning (80%) and Implementing (20%) (cont.)

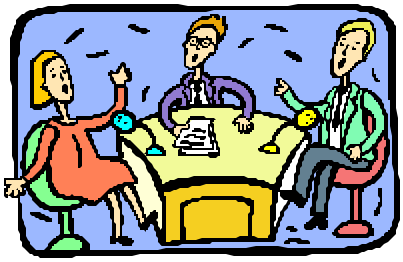
Ten Kaizen Event Rules

1. There is no rank among team members – one person, one vote.
2. Keep an open mind to change.
3. Change is good, more change is better.
4. Maintain a positive attitude.
5. Don't blame anyone for anything.
6. Respect one another.
7. There is no such thing as a dumb question.
8. Plans are only good if they can be implemented. Plans succeed only if the gains are sustained.
9. There is no substitution for hard work.
10. Just do it!

Phase II: Planning (80%) and Implementing (20%) (cont.)

Step 3: Make the Improvements (Rapidly)

- Work with the operators to find solutions,
- Meet with staff to collaborate on new ideas,
- Test new layouts before moving equipment, and
- Train the staff on the new process—be present for a couple of days to ensure little problems are corrected and operations continue to run smooth.
- Re-measure to quantify your improvements



Cautions (cont.)

- Do Lean WITH the people, not TO the people
- Understand the importance of preparation and follow up; it takes more time than actual implementation
- Success only comes with a company culture that supports continuous improvement—key point!

Phase III: Presentation, Celebration & Follow Up

Step 1: The Presentation

- Team prepares presentation.
- Include all pre- and post- data and event results—your dashboard.
- Share what went right and lessons learned.
- Discuss major accomplishments and milestones.
- Circulate results to sponsor group.
- Display results in a central area.

Phase III: Presentation, Celebration & Follow Up (cont.)

Step 2: The Celebration

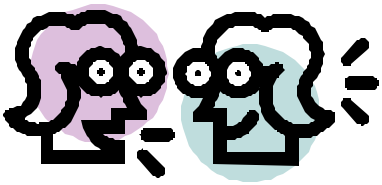
Phase III: Presentation, Celebration & Follow Up (cont.)

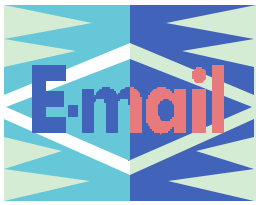
Step 3: The Follow Up

- In many ways, kaizen events are never over:
  - Results must be monitored through observation and audits,
  - Improvements should be continually made,
  - Monitor "to do lists" and complete follow up items ASAP,
  - Contact staff within a week for feedback on the changes:
    - Make a list of their suggestions, and
    - Have staff participate in weekly meetings.
  - Keep tracking and posting results – whatever you track will improve!

Communication

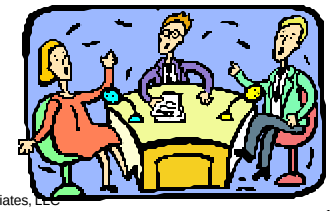
- Makes all the difference in success or failure—key point!
- Announcement from the top communicates serious support.
- Establishing a Process Improvement area (storyboard) enhances communication.
- Posting schedule and steps in conducting kaizen events paints a logical approach (picture).
- Describe what will happen over and over—you cannot over communicate.





Communication (cont.)

- Circulate overall plan of events, areas affected, and benefits expected (why you're doing the kaizen).
- Show before and after photos.
- Publish formal presentation at end of kaizen event.
- Post follow up steps continually as assignments are completed.
- Visually display kaizen efforts and keep them updated with new information so they become common focal points for everyone.
  - Desired behavior: staff members check boards for new information.



Communication, cont.

Ten Arguments Against Kaizen That Need to be Addressed

1. Kaizen won't do any good!
2. It sounds like a good thing, but we still don't want to do it!
3. Looks good on paper, but . . .
4. Costs are already as low as they can possibly get!
5. But we've already been doing things that way!
6. We don't want people looking over our shoulders and telling us what to do!
7. We can't lower costs any more without lowering quality!
8. Everything is going just fine now. Why change it?
9. That's a lousy idea! We already tried that 20 years ago!
10. Look, we understand this stuff better than anybody (so don't tell us what to do).

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Case Study 2: Phlebotomy Dashboard

Kaizen Event	Key Metric	Baseline State	Current State	% Change (actual)	Future State
Phlebotomy	AM draw finished by 5:30 AM	0%	25%	25% ✍	100%
Phlebotomy	AM work completed by 6:30 AM	0%	100%	100% ✍	100%
Phlebotomy	Stat phlebotomy response within 15 minutes	1%	58%	98% ✍	75%
Phlebotomy	AM Phlebotomy Cycle Time	68 minutes	26 minutes	62% ✍	30 minutes
Phlebotomy	AM Technical Cycle Time: receipt to verify	41 minutes	29 minutes	30% ✍	not established
Phlebotomy	AM Turnaround Time: order to verify	109 minutes	55 minutes	50% ✍	not established

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Our Clients' Typical Experience

Lean Metric	Validated Industry Averages[1]	Our Clients' Results
Productivity Improved	45-75%	30-65%
Cost Reduced	25-55%	10-30%
Throughput / Flow Increased	60-90%	50-75%
Defects Reduced	50-90%	20-30%
Inventory Reduced	60-90%	50%
Space Reduced	35-50%	20-25%
Lead Time Reduced	50-90%	40-75%

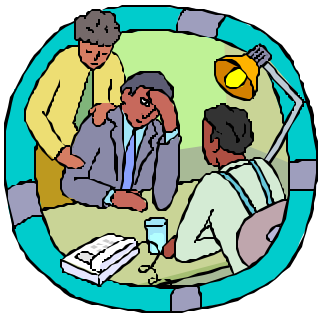
[1] Source: Institute for Healthcare Improvement, 2005

The Four Stages of Change

How People React to Change

Simply put, very differently, depending on three factors:

1. **How much change will disrupt their expectations or perceptions.**
2. **How willing and capable they are to accepting the change.**
3. **Their individual level of control in the situation.**



Four Emotional Stages

1. **Disbelief and Denial**

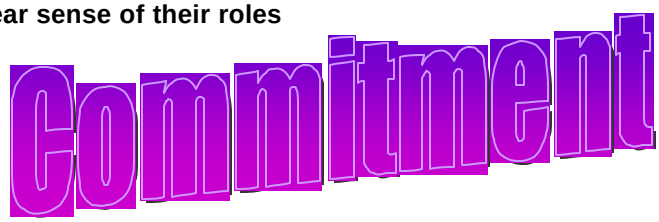
   - **"It won't happen to me."**
   - **"If I just keep my head down, it'll be business as usual."**
2. **Anger and Blame**

   - **"Why should I change?"**
   - **Withdrawal**
   - **Lack of concentration**
   - **Increase in accidents, drop off in quality, absenteeism**

Four Emotional Stages, cont.

3. **Reluctant Acceptance**
   - **People begin to accept**
   - **Start to explore their role**

4. **The Final Stage**
   - **Focus on the future instead of dwelling on the past**
   - **Clear sense of their roles**



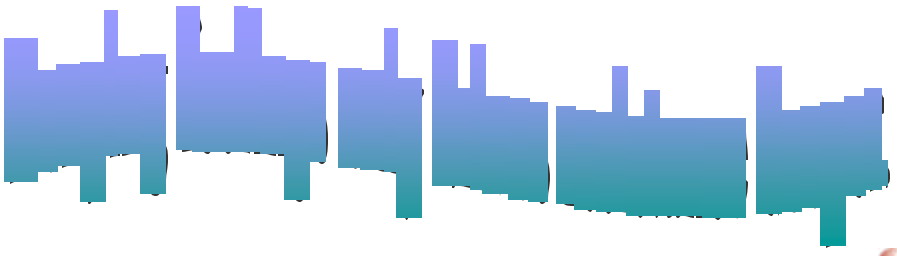
During Denial

1. **Do everything you can to minimize the shock.**
2. **Plan ahead.**
3. **Give staff plenty of information – what the changes will be, who will be affected by them and how.**
4. **Give staff best estimate of the timeframe.**
5. **Give staff a chance to prepare themselves.**
6. **Let the changes sink in.**

You cannot over-communicate now!

During Resistance

1. Listen to what people have to say.
2. Empathize.
3. Don't tell them to snap out of it or pull themselves together.
4. Don't give solutions – just acknowledge their responses and reactions.



During Exploration

1. Give practical encouragement and support.
2. Provide training.
3. Involve staff in planning and setting goals.
4. Focus on short term wins.
5. The response will be good if people can see the positive impact of the change.

Show the benefit of the changes

During Commitment

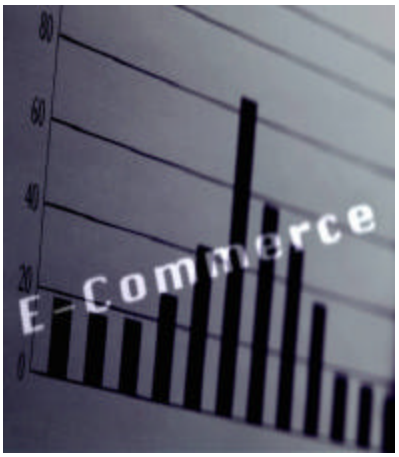
1. Set about consolidating the change.
2. Implement an appropriate cultural change program.
3. Recognize and reward people who are responding well.

Three Truths of Change

1. People do what they create.
2. Some people will NEVER go along.
3. Killing the messenger kills change.

The Attitude Bell Curve

- Use a standard distribution to understand employee attitudes.
- Small group is highly constructive, deeply committed to organization and inherently supportive.
- Another small group is highly disruptive, deeply alienated and inherently resistant.
- Most employees are more or less neutral and can be convinced on the merits.



The Attitude Bell Curve, cont.

- Assume the following:
  - 15% are supportive
  - 15% are resistant
  - 70% are neutral
- Key is to concentrate on the neutral 70% to move them to the right.
- Resisters – some may join the majority of the staff, some may leave.

Tips to Managing Change

1. Be mentally tough.
2. Show determined leadership.
3. Persevere under the most stressful resistance.
4. Don't create more resistance by attempting to fight or control every aspect.
5. Don't take the resistance personally.
6. Set the standard for others to emulate.
7. Exert your focus where the impact is the greatest.
8. Let go of things you can't control.

Selected Bibliography

1. Balle, Freddy and Michael Balle. *The Gold Mine: A Novel of Lean Turnaround.* Lean Enterprise Institute, 2005.
2. Bossidy, L. and R. Charan. *Execution. The Discipline of Getting Things Done.* Crown Business, New York, 2002.
3. Ford, Henry. *Today and Tomorrow.* Productivity Press, New York, 2003. Reprint. Originally published: Doubleday, Page and Company, Garden City, New York, 1926.
4. George, M.L. *Lean Six Sigma.* McGraw-Hill, New York, 2002.
5. Jones, D. and J. Womack. *Seeing the Whole - Mapping the Extended Value Stream.* The Lean Enterprise Institute, Brookline, Massachusetts, 2003.
6. Levinson, W.A. *Henry Ford's Lean Vision. Enduring Principles from the First Ford Motor Plant.* Productivity Press, New York, 2002.

Selected Bibliography

8. Liker, Jeffrey K. *The Toyota Way—14 Management Principles from the World's Greatest Manufacturer.* McGraw-Hill, New York, 2004.
9. Liker, Jeffrey K. and David Meier, *The Toyota Way Field Book. McGraw-Hill, 2006.*
10. Mann, David. *Creating a Lean Culture: Tools to Sustain Lean Conversions. Productivity Press, 2005.*
11. Marchwinski, C. and J. Shook, *Lean Lexicon.* The Lean Enterprise Institute, Brookline, Massachusetts, 2003.
12. Ohno, T. *Toyota Production System. Beyond Large-Scale Production.* Productivity Press, New York, 1988.
13. Rother, M. and R. Harris. *Creating Continuous Flow- an Action Guide for Managers, Engineers and Production Associates.* The Lean Enterprise Institute, Brookline, Massachusetts, 2001.
14. Rother, M. and J. Shook. *Value Stream Mapping Workshop.* The Lean Enterprise Institute, Brookline, Massachusetts, 2002.

Selected Bibliography

15. Rother, M. and J. Shook. *Learning to See- Value-Stream Mapping to Create Value and Eliminate Muda.* The Lean Enterprise Institute, Brookline, Massachusetts, 2003.
16. Westgard, J.O. *Six Sigma Quality Design and Control.* Westgard QC, Inc., Madison Wisconsin, 2001.
17. Womack, J.P. and D.T. Jones. *Lean Thinking. Banish Waste and Create Wealth in Your Corporation.* Simon and Schuster, New York, 1996.
18. Womack, James and Daniel Jones. *Lean Solutions How Companies and Customers Can Create Wealth Together,* Free Press, October 2005.
19. Goodson, R.E. 2002. Read a plant-- fast. *Harvard Business Review, May 2002.*
20. Murphy, M. Research brief: Eliminating wasteful work in hospitals improves margin, quality and culture. Accessed on-line, 9/11/2003: www.murphyleadershipinstitute.com

Thank you!

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