

# A METHODOLOGY FOR MANUFACTURING PROCESS IMPROVEMENT

By

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## **ABSTRACT**

A review of current literature and industry methods in the areas of Quality and Productivity Improvement as well as in the areas of Problem Solving and Process Improvement provides insight into different methodologies that can be used for the purpose of Manufacturing Process Improvement.

This thesis builds upon previous research and industry methods to form a general manufacturing process improvement methodology. Initially this methodology will be presented as a superset of the individual methodologies. Subsequently this superset will be analyzed to form a new methodology that contains many of the same steps as the superset but which has been modified in attempt to overcome some deficiencies. The outcome of this is a multi-level process improvement methodology.

The thesis will also concentrate on specific methods to identify, analyze, and prioritize areas of potential improvement in an effort to form improvement projects. It will describe some tools and techniques that can be used in each of the steps within the above levels.

The ideas presented have been brought about through an actual improvement effort undertaken at a pharmaceutical company to improve a manufacturing process through defect reduction, cycle time reduction, and process simplification.

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This research was carried out jointly with Stephanie (Maggs) McDonald. Chapters 2,3,4, and 5 have been developed jointly with her. For more in-depth coverage of this material and its connection with Design of Experiments as well as into general problem solving, refer to her MIT 1992 SM thesis: *A Methodology for Process Improvement; Optimization of a Coating Process*. Thanks Steffie, this research would not have been as fun without you.

I would also like to thank Bill Obrien, Russ Gilbert, and Denise Hudson at 'Acme' company for their whole hearted support of this research as well as including me into their company in full confidence. The efforts of Ravi Menon are greatly appreciated. His supervision, guidance and support in every area not only made this effort a success but also a thoroughly enjoyable experience. Finally, I would like to thank Bill Baldy, Ben Barber, Deray Burton, the members of the Tablet Inspection Elimination Team, and the members of the Tablet Coating Improvement Team. I wish you all many more successes in the future.

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# **1. INTRODUCTION**

## **1.1 Purpose of Research**

The purpose of this research is to propose an enhanced framework for systematic manufacturing process improvement. This entails viewing, attacking, and correcting various problems or processes through systematic and planned approaches (as opposed to fire fighting activities). These approaches can be defined as improvement *methodologies*. In addition, this research is intended to develop process improvement such that it can be used as a *broad based organizational mechanism* instead of another 'program' aimed at improving business activities. Thus, the general term *Process Improvement Methodology* will be used to define the outcome of this research.

## **1.2 Overview of what is developed in the thesis**

Analyses of efforts in process improvement reveal many interesting and worthwhile methodologies. In this research, a methodology (defined as the **Superset methodology**) obtained by combining the work of many academics, company programs, and experts in quality and productivity improvement is used to review current notions of process improvement. This methodology is then improved and refined. The result is presented as a new manufacturing process improvement methodology (defined as the **Multi-Level methodology**).

## **1.3 Justification of Need**

The use of systematic methods to achieve improvement in operations has been proposed by numerous academic and industry experts. The reason that they make this recommendation is because improvement activities within a company are generally large or complex efforts. The risks involved in these efforts may also be high. Therefore, it makes sense to ensure that any effort to improve a company's

operations is guided to achieve strategic benefits, structured to promote successful results, and optimized to make valuable use of limited resources.

To make systematic improvement easier, there are many process improvement methodologies in print. Some of these are meant to improve quality. Others are meant for productivity improvement. Still others are aimed at problem solving using planned approaches. There are even a few methodologies for general process improvement. The Superset is intended to combine the benefits of these individual methods.

The Multi-Level methodology presented attempts to overcome many of the deficiencies of the Superset and of individual process improvement methods. Such weaknesses include:

- failure to discern the roles of senior management, operations personnel and problem solving teams.
- failure to realize that these roles are similar in nature.
- lack of emphasis on communication between organizational levels during the improvement effort.
- little recognition of the complexities in implementing methodologies.

These characteristics are defined and explained in more detail later in the thesis. The Multi-Level methodology retains many of the benefits of the Superset and incorporates changes to overcome the above weaknesses to achieve an enhanced framework for process improvement.

#### **1.4 Development of Methods**

This research was carried out to take advantage of the work of many individual academic, corporate, and industry efforts in process improvement. The

Superset methodology extracts the advantages of current methodologies as much as possible. However, through the course of this work, it became apparent that a few enhancements could be made to the Superset. The result of which is the Multi-Level methodology. Chapters 2 and 3 present the development of the Superset method and the justification for its improvement into the Multi-Level framework. Chapter 4 develops the Multi-Level methodology more completely. Chapter 5 provides a summary of the benefits of the Multi-Level framework.



## **2. A CASE STUDY IN PROCESS IMPROVEMENT**

### **2.1 Introduction**

The Multi-Level methodology is developed and verified through a process improvement effort undertaken at a major pharmaceutical company. This effort involved a plan to improve the manufacturing performance of the company. It was initiated by senior level management, followed up by middle level management through the creation of specific improvement projects, and implemented using separate cross functional teams for each of these projects. The research was performed by two students who participated as members of the actual process improvement teams. Through this study these researchers were able to:

- understand the details of process improvement efforts.
- apply various activities within the methodologies.
- develop enhanced methodologies.

These studies inspired the creation of the Multi-Level methodology. In addition, the improvement effort contributed significant benefits to the company in terms of cost reductions, yield improvements, cycle time reductions, equipment reliability improvement, and process understanding.

#### **2.1.1 Overview of results**

In the first improvement project, the production yield of solid dosage pharmaceutical tablets was improved by approximately 5% in conjunction with a potential for significant reduction in the process cycle time. These improvements translate into savings of over one million dollars for the company per year. Details of this study will be presented in following sections. This project is still running at the time of this writing. When complete, the end result will be further improvement in yields which will allow for the elimination of 100% manual inspection in the process. This will provide a 50% improvement in cycle time.

In the second project, net yields of a coating process are improved by 8%. This correlates to annual savings of approximately \$300,000. In addition, further savings up to \$600,000 could be achieved. This improvement effort also provided unanticipated benefits in cycle time reduction, equipment reliability, and process control.

## **2.2 Overview of the Company**

### **2.2.1 Company Profile**

The company where these improvement efforts took place, "Acme" (for confidentiality), manufactured solid dosage (tablet) and encapsulated products. Annual sales are in the hundreds of million dollars and manufacturing efforts are undertaken at numerous plants (although only one of these were studied by the researchers).

### **2.2.2 Organizational Initiatives**

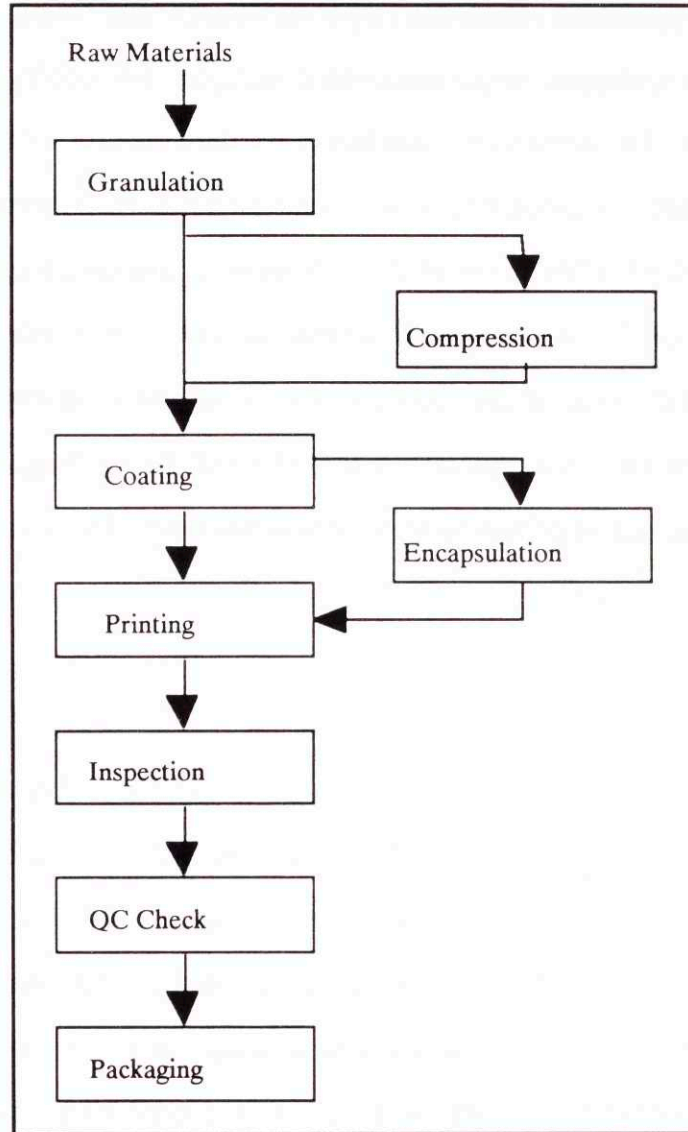
Acme is striving to become a World Class Manufacturer. Initiatives used to achieve this goal include employee involvement and statistically based process control. Both of the improvement projects were carried out using cross functional employee involvement teams. Specifically these were multi-disciplinary work teams consisting of process engineers, scientists, manufacturing operators and supervisors, maintenance technicians, quality control specialists, and the researchers in engineering roles. The Acme process improvement effort highlights the benefits of combining employee participation with structured methods to achieve significant operational benefits.

### 2.2.3 Typical process flow

The typical process flow for solid dosage products is illustrated in **Figure 2.1**. The first step is granulation. Here the raw materials are combined. Next, for tablet products, pressure is applied to the granulated material in specially designed dies forming the tablet. The tablets or granulation are then coated with a thin film to ease swallowing, provide color, or provide additional medicinal purposes. Encapsulated products undergo an extra encapsulation step after coating. The coated tablet or capsule then undergoes a printing operation where the name of the product is printed onto the tablet. 100% manual inspection insures that the outgoing product is free from defects. After the batch has been approved by quality control it is packaged and delivered to the distribution center.

**Figure 2.1**

Acme Process Flow Description



### **3. DEVELOPMENT OF AN OVERVIEW METHODOLOGY**

#### **3.1 Areas of Investigation**

To determine the state of research in the area of process improvement , a literature search was performed to locate areas of study that contain various relevant methodologies. In the process of this review, it was determined that many articles, books, journals, and company programs in the areas of quality and productivity improvement as well as in problem solving techniques contain useful improvement methodologies.

#### **3.2 Developing a Common Reference Frame**

To allow the review to be presented in a concise manner, it became necessary to develop a common reference frame to compare the various methodologies. This was achieved by establishing a list of similar activities presented by the various methods. Subsequently, the list was condensed by taking common activities from different approaches and integrating them into a single representative activity. For example, Kume recommends a step in his methodology which he calls *Analysis: Finding Out the Main Causes*<sup>1</sup>. Hall also recommends a similar step which he calls *Systematic Search for Causes*<sup>2</sup>. Both these steps pertain to structured approaches for hypothesizing, analyzing, and verifying the root causes of manufacturing problems. To facilitate the review, they have been integrated into a step called *Possible Causes Identification*.

The entire list of approaches was condensed in this fashion until only 13 distinct steps remained. These 13 steps cover a broad range of activities ranging from management actions to problem solving techniques. **Figure 3.1** provides a brief

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<sup>1</sup> Kume, 1985, p.198.

<sup>2</sup> Hall, 1987

description of these steps. **Figure 3.2** gives an overview of the various research.

**Figure 3.1**

**Definition of 13 Steps**

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Management Initiative

Establish an environment which recognizes the need and importance of process improvement

Organization for Improvement

Establish an organizational structure for improvement. Establish reward methods.

Definition of Areas & Goals for Improvement

Recognize areas for improvement. Prioritize these and establish obtainable goals.

Project Definition

Establish projects which have potential to help meet improvement goals. Prioritize these based on constraints. Establish means to achieve goals and define success.

Problem Evaluation

Collect information about the current system. Identify process problems that need improvement in order to meet goals established in project definition stage.

Possible Causes Identification

Establish tests for potential process problems. Collect and analyze data.

Selection of a Solution

Evaluate possible solutions. Choose those to be implemented.

Implementation of a Solution

Implement the most promising solution.

Verification of Solution

Verify the results against observations in problem evaluation stage. Determine if success criteria from project definition stage were met.

Standardization of Solution

Make the solution part of everyday operating procedures.

Publication of Results

Make others aware of results for other areas and for confidence in the techniques.

Rewarding for Success

Reward positive results & recognize committed efforts.

Proceed to Next Improvement Effort

Begin it all over again., learning from the past experiences.

---

**Figure 3.2**

**Summary of Research and Company Methods**

	Kume	Juran	Hall	Shingo	Hradesky	Crosby	Kenrick	Florida Power	Robinson	Kawakita	and Light	J & J	Shiba et al	Quality Institute	GM Quality Devices	Spainin	Quality Network	Harris & Firsih	Alcoa
Management Initiative																			
Organization for Improvement																			
Def. of Areas/Goals for Improvement																			
Project Definition																			
Problem Evaluation																			
Possible Causes Identification																			
Selection of a Solution																			
Implementation of Solution																			
Verification of Solution																			
Standardization of Solution																			
Publication of Results																			
Rewarding for Success																			
Proceed to Next Improvement Effort																			

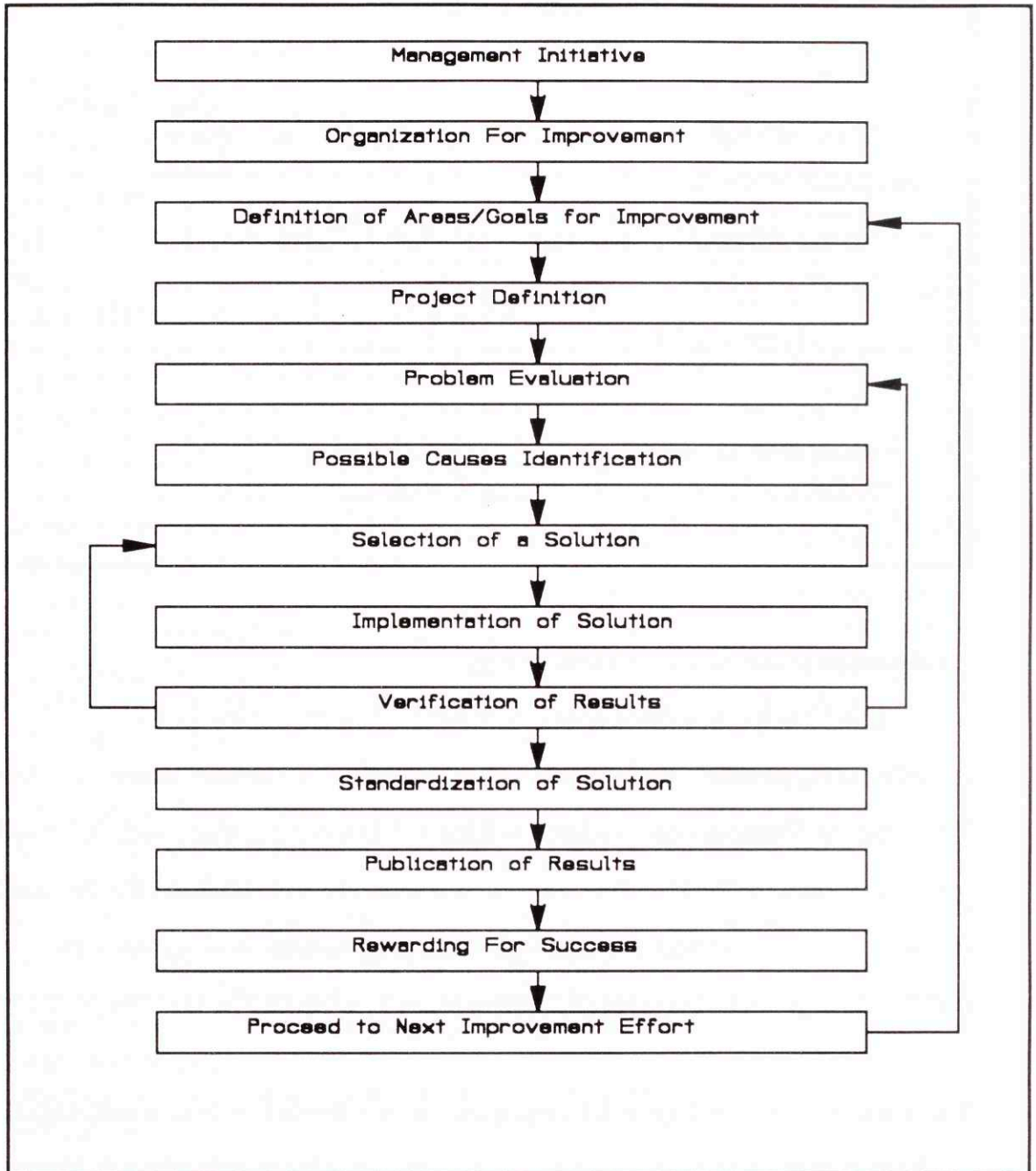
**3.3 Overview of the Superset Methodology**

The 13 steps described above represent a new methodology for manufacturing process improvement. This methodology has been given the name **The Superset Methodology** (outlined in **Figure 3.3**) since it is essentially the union of many individual methods. When viewed as a separate methodology, the Superset provides broader coverage than the individual approaches. It also allows an organization to take advantage of numerous approaches to process improvement.

The summary table in **Figure 3.2** can be used as a reference to locate individual methods that provide coverage in a specific area. It is intended to be a guide to locate expertise in a given area of the Superset. The individual methodologies tend to concentrate on a given area of the Superset. Therefore, a company can benefit by looking closely at a few methods that combine to cover all the steps.

**Figure 3.3**

**The Superset Process Improvement Methodology**





### **3.4 Steps of the Superset**

A brief description of the 13 steps within the Superset is provided below. Each step is highlighted with an example from the case studies where appropriate. In addition, examples from individual methodologies are provided where those methods went into detail or stressed the use of the step.

#### **3.4.1 Management Initiative**

This stage of the improvement process involves assessing the weaknesses of the organization, the advantages that the competition may possess, and the needs of the customer. Indeed, Kendrick states the main question that firms should ask themselves at this time is "where do we need to improve and why"<sup>3</sup>. If a weakness exists (such as quality problems) then the appropriate management initiative should be pushed forward to combat the problem. At Acme Corporation, top management's goal was to obtain a world class manufacturing organization. As a result, improvements were needed to reduce the overall process cycle time and reduce cost through waste reduction. Upper management can be a catalyst for efforts in these areas by establishing clear goals and expectations thorough the use of a structured approach.

#### **3.4.2 Organization for Improvement**

In this step, changes are made within the organization to develop a structure for problem solving and training. For example, management can charter a small team (six to eight people) with the knowledge and authority to attack the problem<sup>4</sup>. In addition, team members are provided with training.<sup>5</sup> For this thesis, both

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<sup>3</sup> Kendrick, 1984, p.123.

<sup>4</sup> GM Quality Network

<sup>5</sup> Hradresky, 1988, p.13

researchers participated in employee involvement teams chartered to improve specific problems. As described previously, improvement efforts were detailed into two separate improvement projects. These were given the names 100% Inspection Elimination and Product B Yield Improvement. Both of the teams on these projects received training in the areas of statistical process control and design of experiments.

In addition to training, reward mechanisms or incentive systems should be created to motivate improvement efforts. Without such a system, the improvement effort could seem like an added burden to its members.<sup>6</sup>

### **3.4.3 Definition of Areas / Goals for Improvement**

At this stage, the strategic goals developed in the management initiative step are converted into project areas for improvement and specific goal that should be met. Choosing the projects to address in order to meet management's strategic goals begins with a prioritized list of areas that need improvement<sup>7</sup> as well as the desired level of improvement<sup>8</sup>. To determine specific goals, cost estimates, interviews and brainstorming are a few tools that can be used<sup>9</sup>. At Acme, the goal of attaining a world class operation was broken down to the areas of reducing cycle time and improving cost through waste reduction. The specific goals in these areas was to reduce cycle time by 50% and achieve \$3M in cost reductions.

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<sup>6</sup>Juran, 1988

<sup>7</sup>Alcoa, 1989

<sup>8</sup>Juran, 1988

<sup>9</sup> Florida Power and Light, 1984, p.18.

### 3.4.4 Project Definition

Once areas or goals of improvement are known, specific projects must be identified and prioritized. Such prioritization can be based on such things as feasibility, cost, and potential benefits. Harris has proposed a prioritization mechanism. In his model the decision variables for choosing a particular project include such things as impact, do-ability, timing, and fit with product strategy.<sup>10</sup> At Acme two projects were initially generated. The Inspection Elimination project was created with the charter of increasing tablet product quality to a point where 100% manual inspection could be replaced with statistically sampled inspection. Since manual inspection of millions of tablets is extremely time consuming, tedious, and stressful, eliminating this process step would greatly improve the manufacturing cycle time and achieve the first target of a 50% cycle time reduction. The second project was to increase the yield of Product B (actual name omitted for confidentiality) which was known to have high waste standards. The raw materials for this product were also extremely expensive. Therefore, by increasing yield (reducing waste), the cost reduction target could have been met. Although these projects were chosen such that, if successful, they would meet the organizational goals, the project definition actions and methods were not performed with the same level of detail as this methodology step proposes. The complications of this action will be presented in a later section.

In addition to prioritizing which projects to attack first, "measurable goals and a valid measuring system"<sup>11</sup> should be established. It is also important for the team to "establish a project plan at this stage of the process so that for the duration of the project the members will maximize their time and efforts and maintain the focus

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<sup>10</sup> Harris, 1990, p.36.

<sup>11</sup> Alcoa, 1989, p.6.

and direction of activities"<sup>12</sup>. Once the project has been chosen, a measurement system and goal defined, and a charter established the next step is problem evaluation.<sup>13</sup>

### **3.4.5 Problem Evaluation**

Once the project is established, specific problems within this project area must be determined. The first step is to determine the various causes of poor performance. To become aware of the problem (or problems) one must be able to notice "the difference between what is expected and what is actually occurring"<sup>14</sup>. Several tools exist for this process. For example, a KJ (a brainstorming tool) can be used to recognize a problem exists, determine the extent of the problem, and generate a hypothesis for the source of the problem.<sup>15</sup>

For the Product B yield improvement project, a cause and effect diagram was used to determine that problems existed in the areas of process controls, equipment, and operating parameters. These problems were analyzed and an immediate course of action chosen. Three problem efforts were necessary for yield improvement: install a control system, improve equipment problems, and optimization of process parameters.

### **3.4.6 Possible Causes Identification**

Once the problem area is established, root causes must be identified. The first step is to measure the extent and characteristics of the problem. These include

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<sup>12</sup> Hradesky, 1988, p.31.

<sup>13</sup> Harris, 1990, p.36

<sup>14</sup> Robinson, 1991, p.230.

<sup>15</sup> Kawakita, 1980, p.9.

asking the for M's (me, machine, material, method)<sup>16</sup>. Using data, possibly collected through the use of CIM technology<sup>17</sup>, and SPC analysis to locate problems.<sup>18</sup> In addition asking who, what, where, when, how, and how much can help pinpoint root causes of the problem as well<sup>19</sup>. Information about the process can also be obtained by asking questions, brainstorming and collecting data.<sup>20</sup> With this data in hand, hypotheses can be generated for the source of the problem. Small scale or designed experiments can then be used to test these hypotheses. Next, data is collected to discern if the root cause is indeed found. If so, the last step of the possible causes identification stage can occur - generation of possible solutions.

At Acme, the optimization of yields for product B effort followed many of these steps. Historical data and cause and effect diagrams were used to generate hypotheses about the root cause of coating problems. A designed experiment was planned and run to determine the cause. Results from the experiment indicated that three parameters were critical to increase yields. The results also indicated the optimal settings for these parameter (the solution to the problem).

### **3.4.7 Select a Solution**

After the possible solutions of the problem are determined, they are then screened to determine which solution will solve the problem with the most benefit and least cost. Robinson states one should "consider factors such as the feasibility of implementation and the cost, time, and labor required, balancing these factors against the benefits of implementation, the adaptability to other situations, and the

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<sup>16</sup> Robinson, 1991, p.232.

<sup>17</sup> Firsty, 1990, p. 29 and Harris, 1990, p.14.

<sup>18</sup> Juran, 1988

<sup>19</sup> GM Quality Network

<sup>20</sup> Scneiderman, 1991

expected life of the benefits"<sup>21</sup> when choosing a solution. Several other authors refer to solution selection matrices as well. These include Alcoa and Florida Power and Light.<sup>22</sup>

### **3.4.8 Implementation of a Solution**

Once a solution is selected, it is necessary to implement it. Often a small scale test is useful. The intent is to determine if the appropriate solution has been selected. This stage involves communication with various affected departments, establishing an implementation plan, educating and training employees of the changes and dealing with problems (i.e. having contingency plans) during the implementation.<sup>23</sup>

### **3.4.9 Verification of Results**

The purpose of this step is to verify the results obtained in the implementation step against observations in the problem evaluation stage and initial goals for improvement. If the level of improvement is insufficient, the process should be reiterated from the selection of a solution step to implement the next prioritized that will meet the goals. If the area of improvement activity has not been improved at all, one should return to the problem evaluation step to re-examine the source of the problem.

There are many ways to verify the results, these include taking measurements coupled with evaluation<sup>24</sup>, defect analysis<sup>25</sup>, and analysis using product, process,

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<sup>21</sup> Robinson, 1991, p.255.

<sup>22</sup> Alcoa, and Florida Power and Light, 1984, p.44.

<sup>23</sup> Robinson, 1991, pp. 258-9. and Alcoa, p.17.

<sup>24</sup> Bitran, p.4.

<sup>25</sup>Juran, 1988

system and financial audits<sup>26</sup>. GM quality Network recommends that a root cause solution has been found if one can "turn the problem on and off"<sup>27</sup>

#### **3.4.10 Standardization of Solution**

If the solution is successful, the next step is to make the solution a part of every day operating procedures. To do so one must "modify the management systems, operating systems, practices, and procedures to prevent recurrence of this and all similar problems"<sup>28</sup>. This may necessitate a change in documentation, training, communication, control, and/or equipment. At Acme for example, new operating procedures were established after the optimal settings for the Product B process were determined.

#### **3.4.11 Publication of Results**

Complete communication of the results of the effort should be made. In addition, the methods used, the findings, and the solution should be made known and documented. These are useful for others who come in contact with the manufacturing processes or other similar setups. This can be accomplished through project documentation, reports, presentations.

#### **3.4.12 Reward for success**

Employees responsible for improvement activities should be recognized for their efforts to encourage continual improvement efforts. Monetary or honorary awards (such as certificates, plaques, medals) can be distributed. Name recognition

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<sup>26</sup> Hradesky, 1988

<sup>27</sup> GM Quality Network

<sup>28</sup> GM Quality Network

by the top management of the company can be used as well<sup>29</sup>. Recognition can take place after milestones are accomplished for a large project, or at the end of the project (smaller scope).

### **3.4.13 Proceed to Next Improvement Effort**

Upon completion of a specific improvement effort, activities should shift to the next most important problem area or project facing the organization.

## **3.5 Analysis of the Superset**

A careful analysis was performed, using knowledge gained from the Acme case study to further enhance the framework developed in the Superset. This analysis located four weaknesses associated with the Superset:

- The division of roles and responsibilities in an organization for process improvement are not clarified. Upper and middle level management as well as problem solvers need to execute different tasks within the Superset.
- The similarities in actions of different levels of the organization are not taken into account. There are multiple levels of data collection, prioritization, and implementation which are difficult to identify using the Superset.
- Communication between levels of the organization is not included as a separate activity. Coordination of process improvement activities requires strong communication links within the organization.
- The Superset presents improvement efforts within an organization as a serial process. They are usually non-serial and repetitive activities.

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<sup>29</sup> Robinson, 1991, pp.287-8.



### 3.6 Improving the Superset

The previous problems represent an opportunity to modify the Superset and develop the Multi-Level process improvement methodology. The above analysis along with the case study have been instrumental in forming the Multi-Level approach. All four issues have been incorporated into its structure. Understanding these features provides useful guidelines for establishing improvement as a broad based organizational mechanism.

## **4 The Multi-Level Process Improvement Methodology**

### **4.1 Introduction**

As mentioned throughout the course of this thesis, a new framework is developed such that it retains the benefits of the Superset and addresses its weaknesses. The areas of enhancement involve:

- specifying the roles of different levels of the organization
- taking advantage of the similarity between activities at each levels
- stressing the importance of communication and support throughout the company to achieve improvement
- handling the complications that arise during implementation

The Multi-Level methodology brings each of these areas together in order to create a methodology which involves the whole company and which helps guide an organization through the difficult tasks involved in obtaining improvement. It is presented as a methodology with three distinct levels of action for the company. The first level (Level I) is meant for senior management. The second (Level II) is for middle management and senior technical personnel. The last level (Level III) is meant for problem solving efforts which are usually carried out by teams containing cross functional members. This final level, however, can also be broken down further into sub-levels. The following sections describe the need for these enhancements and, where needed, provide hypothetical or Acme study based examples.

### **4.2 Division of Roles**

The first enhancement in the Multi-Level methodology is the division of roles for each level of the organization. A close analysis of the Superset uncovers that the majority of its steps can be separated into three distinct levels of responsibility. For example, *management initiative*, *organization for improvement* and *areas and goals for*

*improvement* can best be performed by upper management levels. Once the stage for improvement efforts has been set, the next level down must execute the *project definition* and *problem evaluation* steps to determine, specifically, where efforts should be concentrated to meet upper management objectives. Finally, the last level is performed by those individuals who most keenly understand the processes. It is at this level where *possible causes identification*, and *solution selection*, *implementation*, *verification*, and *standardization* occur. Although this last level is considered a single level in the Multi-Level methodology, there are actually numerous sub-levels defined within it. More complex improvement projects will contain sub-levels, an example of which will be provided in a later section. **Figure 4.1** shows the break down of responsibilities (in terms of the original Superset steps) at each level.

Not all of the thirteen steps fit neatly into these three levels. Several of the steps are conducted by more than one group. These include *publication of results*, *reward for success*, and *proceed to next improvement effort*. These efforts will be included elsewhere in the Multi-Level method.

**Figure 4.1**

**Division of Roles**

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**Level I**

<b>Management Initiative</b>
<b>Organization for Improvement</b>
<b>Definition of Areas &amp; Goals for Improvement</b>

**Level II**

<b>Project Definition</b>
<b>Problem Evaluation</b>

**Level III**

<b>Possible Causes Identification</b>
<b>Selection of Solution</b>
<b>Implementation of Solution</b>
<b>Verification of Results</b>
<b>Standardization of Solution</b>

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At Acme, the Vice President of Operations set the objectives of the manufacturing organization as:

- a 50% reduction in the manufacturing cycle time.
- a reduction in operating cost of \$3M through waste reduction.

It was unclear what methods were used to determine these values. However, when the plant, engineering, quality and research managers met, they did create

improvement projects which, hopefully, would fulfill these objectives. These projects in turn were executed by engineers, manufacturing supervisors and operators, as well as research specialists. This process of transforming performance objects into tangible efforts is realistic in most manufacturing organizations. A methodology which is designed to be an integral part of a company's operations should not try to fight this process but take advantage of it towards effective process improvement efforts.

In addition, as hinted earlier, many companies do not recognize the need to separate activities into these levels and if they do separate them, decide on what roles each level should perform. Acme managers translated the goals of the Vice President into tangible improvement projects. However, they did not pick up the responsibility of defining the projects clearly. The result was that the Inspection Elimination project was guided toward reducing defects in the printing process (refer to **Figure 2.1**). Later analysis revealed that to reduce defects to a point where 100% inspection could be replaced with sampled inspection, the team needed to address defects arising in the coating process. However, the team was made up of personnel familiar with printing only. Therefore they did not have the skills necessary to attack coating problems.

### **4.3 Similarity Between Levels**

The Multi-Level methodology takes advantage of the hidden similarity between various steps in the Superset. This helps to simplify the methodology and concisely define the requirements of each level of the organization. In total, there are more steps in the Multi-Level methodology. However, for each level of the organization, there are clear responsibilities. In this section, four of these steps will be defined. Later, another will be added for a total of five steps in each level.

Although not readily apparent, there is similarity between some of the Superset steps when you view them as being performed by different levels of the organization. For example, *Definition of Areas & Goals for Improvement* involves a great deal of prioritization to determine the few key goals that the company should aim to achieve. *Project Definition* also requires the company to prioritize the many potential projects which can be undertaken to reach the above goals. Finally, *Solution Selection* involves prioritization to layout the most feasible solution to process problems. It is clear that upper level managers should define the goals of the organization, that middle managers and senior technical staff should come up with potential improvement projects and that engineers and operational personnel should determine the best solutions to their problems. Therefore these steps fit easily into level I, II, and III respectively. Other activities from the Superset can be broken down and applied to the Multi-Level methodology in similar fashion.

To carry the task one step further, the similar activities were also given similar titles. For the above example, all three were given the step title *Prioritize*. **Figure 4.2** defines four similar activities between levels in the methodology:

**Figure 4.2**  
Step Names for Similar Activities

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IDENTIFY	ANALYZE	PRIORITIZE	EXECUTE
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The Multi-Level method states that each level of the company should go through activities that involve identification, analysis, prioritization, and execution. Obviously the specifics of these activities and their goals will be different for each organizational level. The following table clarifies these activities with respect to the

level. For Level I or upper management steps, the activities in **Figure 4.3** are suggested:

**Figure 4.3**  
**Level I Activities**

IDENTIFY	ANALYZE	PRIORITIZE	EXECUTE
<ul style="list-style-type: none"> <li>- Identify the need for improvement</li> <li>- Identify the areas for improvement</li> </ul>	<ul style="list-style-type: none"> <li>- Determine areas and level of weaknesses thru <b>benchmarking</b></li> <li>- Define the organizational weaknesses that hinder improvement</li> <li>- Develop courses of action to improve organizational weaknesses</li> </ul>	<ul style="list-style-type: none"> <li>- Prioritize weaknesses against strategic goals of the organization</li> <li>- Select the appropriate organizational course of action</li> </ul>	<ul style="list-style-type: none"> <li>- Communicate areas that should be improved and their desired goals</li> <li>- Execute organizational changes such as creating teams and providing training.</li> </ul>

In Level II, or middle management, the activities in **Figure 4.4** are recommended:

**Figure 4.4**  
Level II Activities

IDENTIFY	ANALYZE	PRIORITIZE	EXECUTE
<ul style="list-style-type: none"> <li>- Identify projects that show potential to meet process improvement goals</li> </ul>	<ul style="list-style-type: none"> <li>- Quantify the extent of weakness in each of the projects</li> <li>- For each project, determine specific processes causing problems</li> <li>- Analyze the requirements of each project; Cost, Time, Resources, Etc...</li> </ul>	<ul style="list-style-type: none"> <li>- Choose the projects to execute based on potential, resources, cost, time, etc...</li> <li>- Chose process(es) of focus for each project chosen</li> </ul>	<ul style="list-style-type: none"> <li>- Establish &amp; execute schedules, budgets, resources, measurements, and other project activities</li> </ul>



Finally the activities for Level III are provided in **Figure 4.5**:

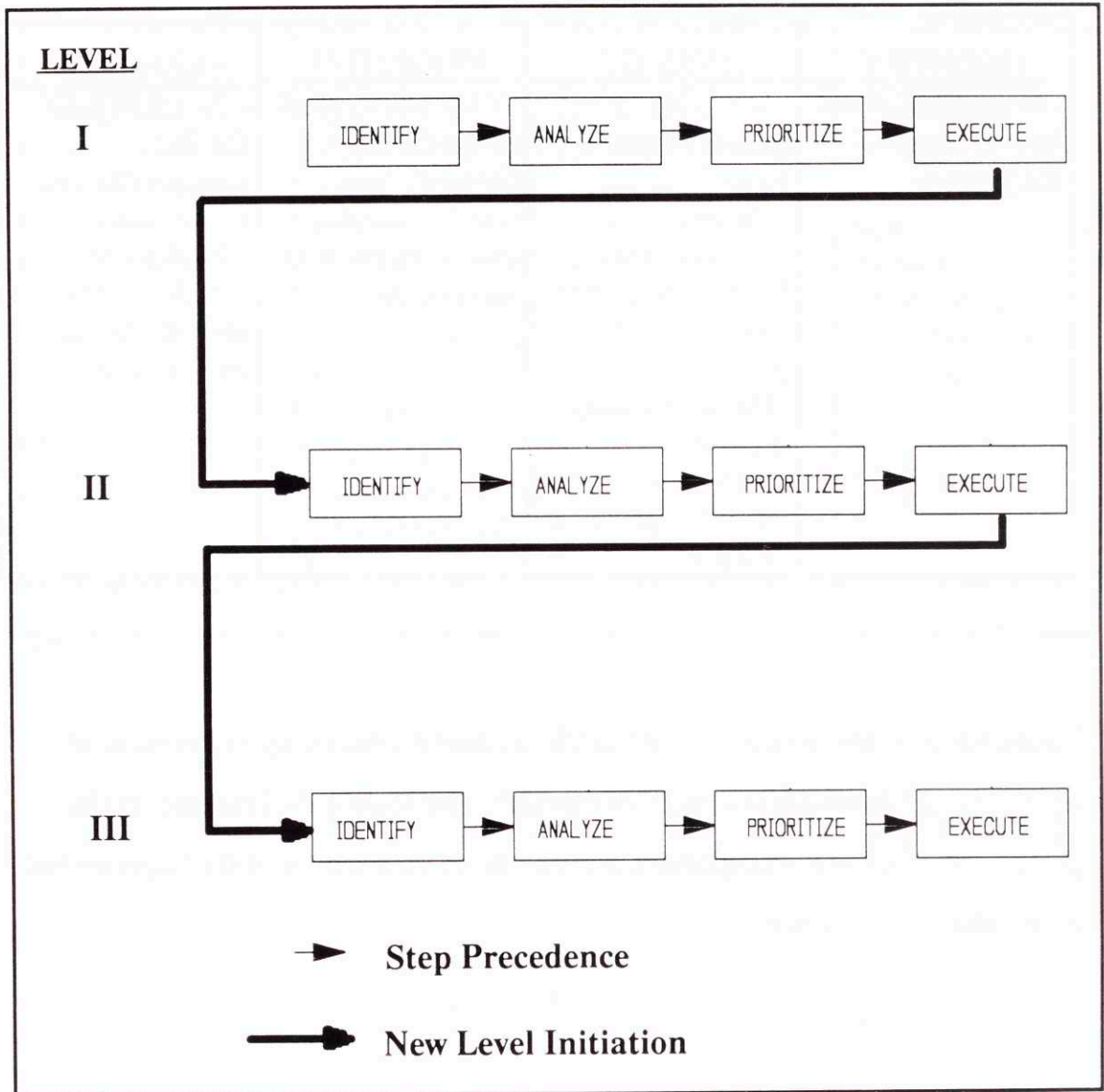
**Figure 4.5**  
Level III Activities

IDENTIFY	ANALYZE	PRIORITIZE	EXECUTE
<ul style="list-style-type: none"> <li>- Brainstorm about how to improve the process</li> </ul>	<ul style="list-style-type: none"> <li>- Establish measurement system</li> <li>- Collect data/perform DOE to determine root causes of problems</li> <li>- Develop possible solutions to problems</li> <li>- Test out potential solutions</li> </ul>	<ul style="list-style-type: none"> <li>- Choose course of action (solution) based on time, feasibility, cost, resources, prob. of success, etc...</li> </ul>	<ul style="list-style-type: none"> <li>- Establish plan for final implementation of solution</li> <li>- Implement solution in the manufacturing environment</li> </ul>

**Figure 4.6** provides an overview of the Multi-Level methodology at this stage of development. Although still far from complete, the Multi-Level method, at this point of development, incorporates many of the same activities of the Superset but in an enhanced structure.

**Figure 4.6**

**Multi-Level Methodology:  
Similar Steps Between  
Improvement Levels**



#### **4.4 Grounding Hypotheses with Data**

Another benefit realized by separating the activities into similar steps between the Levels is that there is constant verification of direction at each level. For example, in Level I, competitive benchmarking and other analyses are performed to verify that the weaknesses identified are actually important. Perhaps defect levels are assumed to be too high by upper management. An industry comparison may reveal that although the levels are not higher than the competition, significant competitive advantage can be gained by increasing quality. Therefore an improvement effort in this area is initiated. Subsequently in Level II, it is hypothesized that most of the defects come from product A and that two key process steps contribute to these losses. Analysis of defect data will help to prove this fact before initiating problem solving projects. Progressing further down to Level III, the problem solving team may guess at possible causes for these defects. A careful SPC analysis can pin point the true root causes allowing efficient resolution to occur.

There are many benefits obtained by using this procedure. First, to even allow for this technique to be used, there must be significant data gathering and analysis. This promotes a better understanding of the companies operations at all organizational levels. Second, the ability to constantly monitor the direction of the improvement effort provides a better chance for improvement success which will lead to competitive advantage. Finally, the use of data for decision making requires that all hypothesis and intuitions be backed by facts. This promotes improvement direction which is more systematic and less judgmental.

A major reason for companies not to follow this approach is the lack of adequate data. At Acme, the failure to accurately define the inspection elimination project

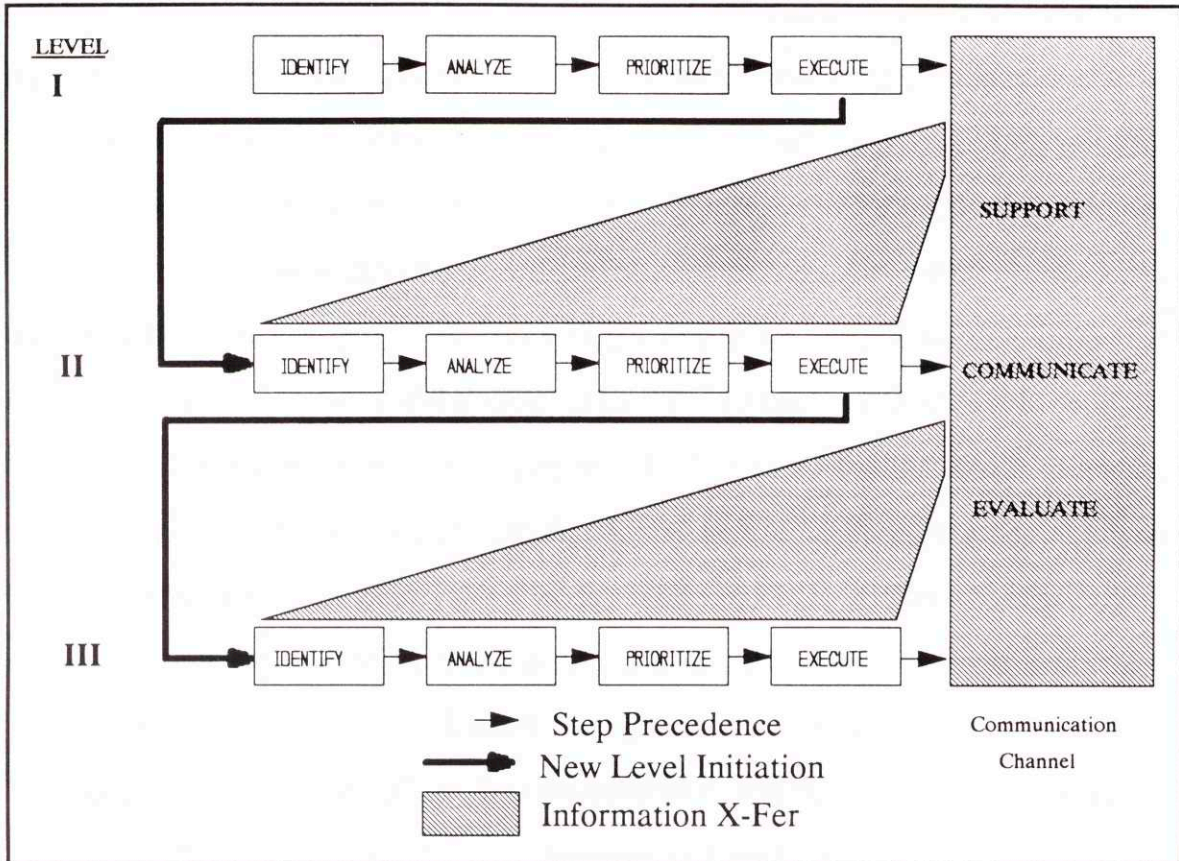
resulted from the lack of data and the subsequent analysis. If the data was available and analyzed, the team or a separate project could have been set up properly from the beginning thus saving months in the realization of improvement benefits. The result of not performing this analysis was noticed by the Inspection Elimination team when after months of trying to improve the printing process, defects were still not at a level where 100% inspection could be eliminated. A back up analysis revealed that coating defects were the cause of most defects. When the team approached management with their problem, it was decided that a separate project and team would be formed to improve coating quality.

#### **4.5 Communication, Support, and Evaluation**

Management must be able to insure that all activities are capable of being completed at each level. In order to do this, communication and support must exist at each level. Middle management (Level II) most provide support for the those individuals seeking to improve a process (Level III) while ensuring that this improvement will meet the goals from Level I. If the Level III team is not in communication with management and vice versa, then management won't be able to help or will not understand how to provide the necessary support. These interactions are represented in **Figure 4.7**. The vertical support, communication, and evaluation box is considered the information conduit through the company for improvement activities. The shaded areas connecting this conduit to the activities of Level II and III represent information transfer from improvement steps to other organizational levels. These communication channels are all two directional.

**Figure 4.7**

**Multi-Level Methodology:  
Complete Diagram**



**4.5.1 Upper and Middle Management Communication and Support**

Management communication and support is useful at all stages of the improvement process. For example, upper management can provide support to the Level II prioritization activity by providing strong communication of corporate goals. When problem solving teams conduct experiments in the Level III analysis step, management can provide an extra nudge to get departments to work with each other in addition to opening up production time for experimental runs. Upper management can also help by granting approval for experiments that a problem

solving team wants to do. This approval may ease the way for commitments to be made from planning, production, and quality control departments.

#### **4.5.2 Informing Other Levels**

Management and project teams at all levels need to communicate to others their progress and problems. This can be done in the form of formal presentations, progress reports, informal meetings, and final reports at the completion of activities. For example, the newly formed coating quality team at Acme had determined that the equipment used in the coating process was not up to requirements. Most of this equipment is extremely expensive and since there was a general push in the company to cut capital expenditures, the team assumed that it had to improve coating quality without major new equipment purchases. As it turned out, the project was able to provide enough benefit to the company that management re-prioritized its capital budgeting outlays. Good communication from the team to management could have helped them get equipment capital requests in place much earlier and placed team efforts at locating the appropriate hardware instead of spending valuable time on the old equipment.

#### **4.5.3 Evaluation of the Improvement Effort**

The final step for all levels is to ensure that the objectives were met. In Level I, this would be to determine if the goals dictated were actually met and if they were, whether the strategic benefits from the improvement are realized. In Level II, managers should ensure that the improvements were obtained by the project efforts and whether these met the goals of upper management. In the next section, the procedure to follow when improvement efforts are not successful will be presented. Finally, Level III personnel should evaluate the success of their efforts in solving problems and improving the manufacturing processes.

## 4.6 Execution Flow and Iteration Within Improvement Levels

As mentioned, there is a procedure to follow when improvement efforts do not meet their desired outcomes. This procedure will be described in this section, but first the general execution flow within a level must be described.

### 4.6.1 Execution Flow

**Figure 4.8** provides a simple diagram of a single improvement level. If we use the example of the coating quality improvement effort, a better understanding of the execution of a level can be provided. First, the potential causes of poor coating quality were hypothesized at the *Identify* step. Next, the team attempted to determine which of these causes was the root cause at the *Analysis* step. This involved first determining a measurement method to track coating quality closely and collecting operational data to correlate process characteristics with coating quality. At this stage the team determined there were numerous problems with the equipment. Since they initially thought that capital was short, the team concentrated on small equipment upgrades and various process changes as potential solutions to the problem. These solutions were then ranked in the *Prioritize* step. The process of this ranking could have been much more systematic. The result was that the chosen solutions were decided by influential members of the team. These solutions were then implemented in the *Execute* step. Finally, the solution was evaluated using the measuring system developed in the *Analysis* step. This evaluation revealed that the small equipment changes which were implemented did not provide sufficient quality improvement.

### 4.6.2 Iteration within a Level

To continue with the above example, the coating quality improvement team decided to first go back to their list of potential solutions and implement another

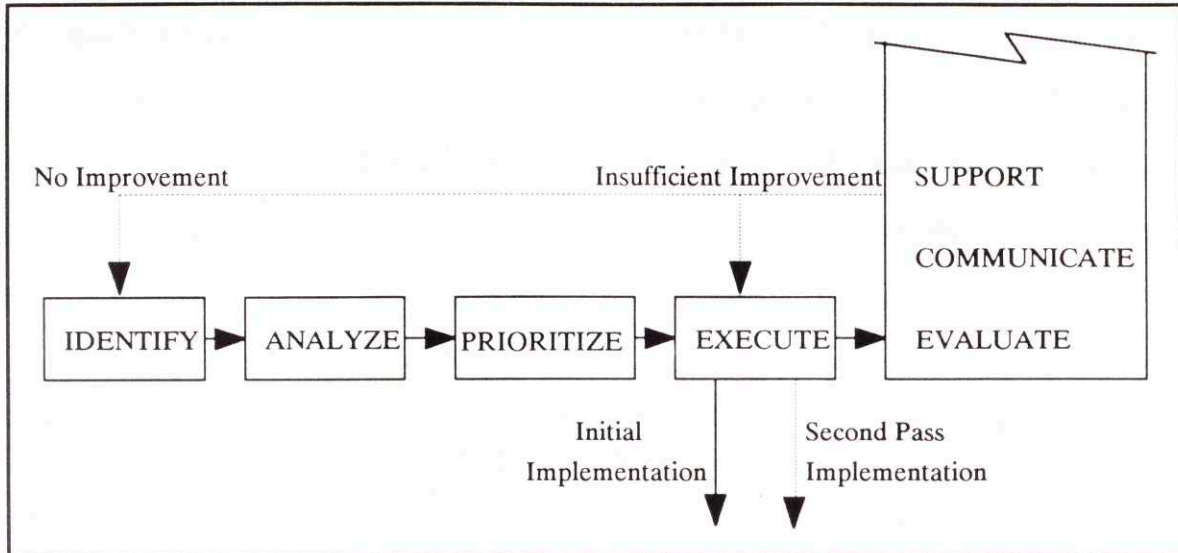
small equipment upgrade. This process is shown in **Figure 4.8** as the dotted line from the *Support, Communicate, Evaluate* block back to the *Execute* block. This was possible since the team developed a prioritized list of solutions in the first pass through the level. This process can be considered the first possible form of iteration.

After the team implemented the next pass of equipment upgrades, there was still insufficient improvement. It was at this time that the team approached management with the dilemma that they could not go further without major equipment changes. As mentioned, management allowed the team to make major changes provided the team justified these changes. This process is depicted in **Figure 4.8** as the dotted line going back to the Identify block. The reason for this is that the team needed to go back and examine the problem again in light of the information gained from the first two passes and from the ability to make major process changes. In addition, the team needed to analyze the improvement effort with the goal of providing justification for new equipment purchases. At the time of this writing, Acme is waiting for a vendor to manufacture a major new piece of process equipment.



**Figure 4.8**

**Multi-Level Methodology:  
Process Flow & Iteration**



**4.7 Implementation Issues**

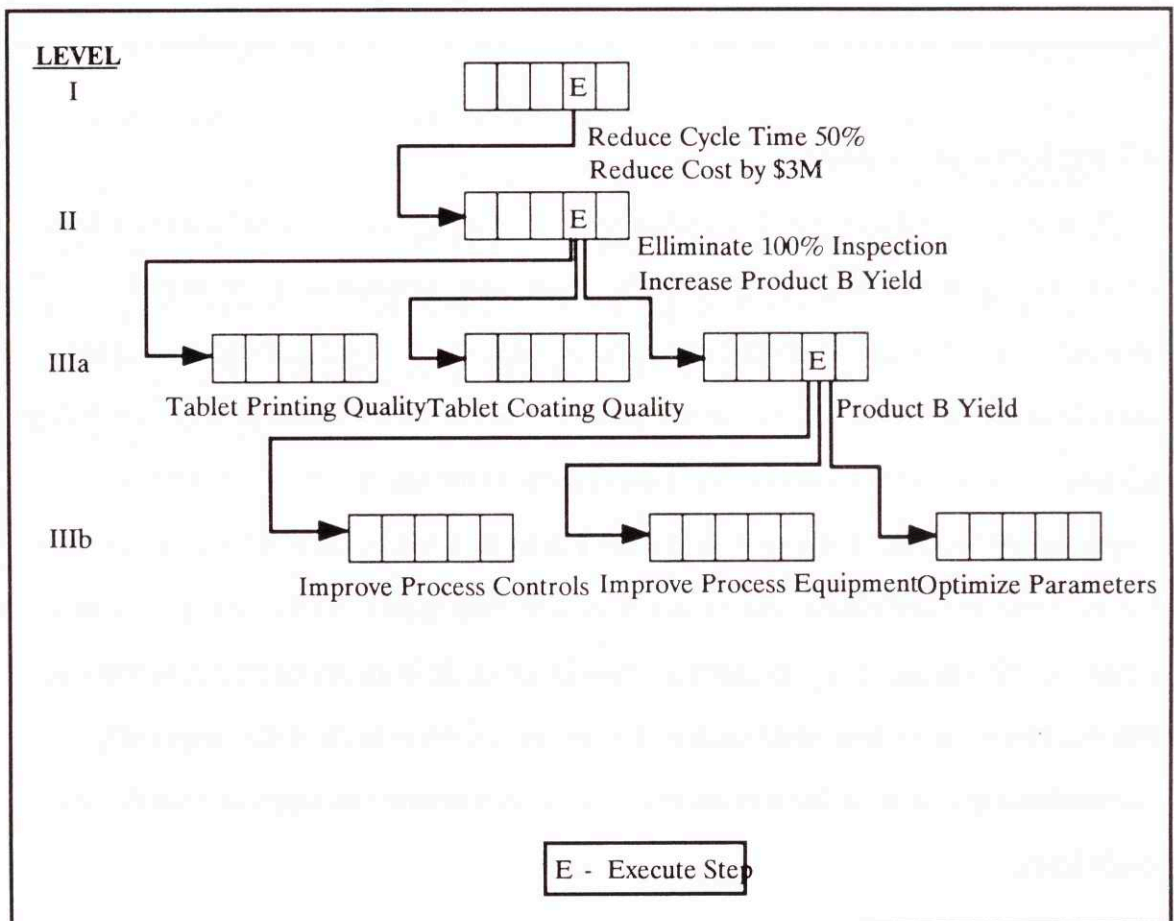
The majority of process improvement methodologies are in the form of a flow chart. This gives the impression that the steps occur sequentially. In actual implementation, some tasks are executed serially, but many others are executed asynchronously. In addition to this aspect, the Multi-Level methodology also brings up another implementation issue. This relates to the recursive nature of the improvement levels. For example, Level I activities may spawn off two or more Level II project definition efforts which in turn may spawn off many improvement projects. This feature is prevalent in most large scale improvement initiatives but has not been easily described within the context of present (and the Superset) methodologies. It is called a recursive spawning because the steps are similar in each level.

### 4.7.1 Recursion (Project, Problem Generation)

In the analysis steps of Levels I and II, many courses of action are determined after performing the analysis. The prioritization steps determine which of these actions should be executed. This potential generation of multiple efforts is represented in **Figure 4.9**. For Acme the boxes represent each activity (identify, analysis, prioritize, execute, support, communicate) that occur over time.

**Figure 4.9**

#### Multi-Level Methodology: Recursion Description



In the Acme example, Level II initiated three projects to meet the goals of Eliminating 100% Inspection and Increasing Product B yields. These include improving *Tablet Printing Quality*, improving *Tablet Coating Quality*, and increasing *Product B Yield* projects. Subsequently, the Product B Yield Improvement Effort generated three sub-projects. These include *Improve process Controls*, *Improve Process Equipment* and *Optimize Operating Parameters*.

#### 4.7.2 Execution Precedence

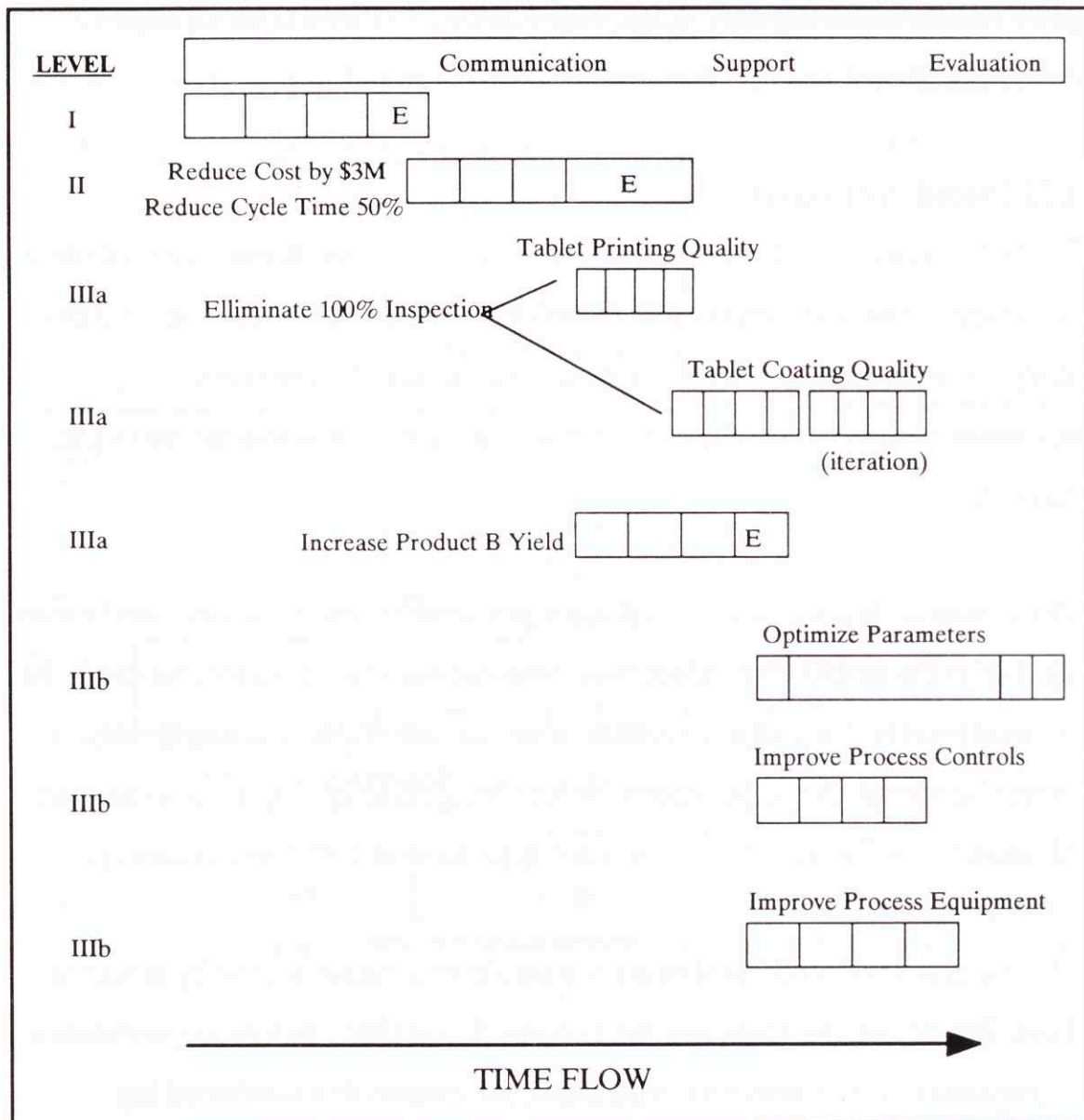
The improvement efforts generated in Level I and Level II can occur serially or in a staggered fashion. **Figure 4.10** demonstrates this phenomena using the Acme study. This diagram also shows the continuous nature of support and communication between the groups represented by the bar across the top of the diagram.

Three projects began at the Level II stage and were executed. As described earlier, the Tablet Printing Quality Project was initiated first, after initiating changes in the printing process, it was determined that a new project, Tablet Coating Quality, should be started. Also, the process for improving tablet quality was also iterated. Meanwhile, the Increase Product B Yield Improvement Effort was underway.

The Increase Product B Yield Improvement Effort is rather interesting in that at Level IIIa it generates three new sub-projects (Level IIIb). Before an optimization of parameters experiment could take place, the controls that monitored key parameters and basic equipment problems needed to be addressed. This precedence relationship is illustrated in **Figure 4.10**. As a result, the analysis step of the optimize stage could not be completed until the controls and equipment projects were finished.

**Figure 4.10**

**Multi-Level Methodology:  
Parallel Activities & Precedence  
Between & Within Levels**



## 5. Summary

The Multi-Level methodology provides an enhanced version of the super-set methodology which was derived from literature sources. Through examples from the two Acme improvement efforts, several major points have been highlighted. Specifically, the Multi-Level methodology provides:

- Multiple levels which define the roles of senior management, operations management, and problem solving teams. This helped ensure that improvement is a part of business and not just another 'program'.
- Identification, analysis, prioritization, and execution efforts are included in each level. The purpose is to set a course of action and efficiently execute it as well as to provide a simple framework.
- Communication between the organizational levels is an integral part of the methodology. This will provide direction for complex or broad scope improvement efforts.
- The levels are designed such that they overlap each other with respect to time. Realistic improvement efforts are spawned processes within an organization where a set of upper management directives can translate into numerous process improvement projects.
- The implementation of the Multi-Level methodology provides an understanding of asynchronous implementation efforts. For example, should a group tackle multiple 'suspected' problem areas in parallel fashion or should they go after them in a prioritized serial way? The Multi-Level methodology allows for either path to be taken.

## **6. PROJECT IDENTIFICATION, ANALYSIS, and PRIORITIZATION**

### **6.1 INTRODUCTION**

The Multi-Level approach to process improvement emphasizes optimizing the resources of the company towards the most significant problems at hand. The process never actually ends. Rather, it progresses in cycles where key problems are identified, analyzed, prioritized, and attacked. These cycles are guided by the strategic direction provided in Level I of the methodology. They are completed by the problem solving approaches in Level III and beyond.

In this chapter, the transformation from improvement goals to specific improvement projects takes place. For example, the goal may be to improve the companies overall quality of products. The steps provided in this chapter will help to convert this non-specific goal into numerous improvement projects. Perhaps one for each different product made by the company. These projects are defined such that they are the optimum method of achieving the goals brought forth by senior management in Level I given the resources and time available. They are subsequently passed on to problem solving efforts in Level III for final execution. Maggs<sup>1</sup> provides in-depth coverage of the steps in Level III along with specific examples from the Acme study.

Three components of the Multi-Level Methodology will be presented; Project Identification, Project Analysis, and Project Prioritization. Project Identification involves a first pass attempt at defining project scopes. Project Analysis provides in-depth awareness of improvement requirements so that better project decisions can

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<sup>1</sup> Maggs, 1992

be made by using factual information. Finally, Project Prioritization involves combining the resources of the company with the requirements from project analysis to select the most appropriate improvement projects.

## **6.2 RESPONSIBILITIES**

Those responsible for defining improvement projects need to understand the strategic goals presented by upper management. In addition, they must not be constrained by organizational, technical, or thought boundaries. "Project selection and evaluation decisions are often confounded by several behavioral and organizational factors. Department loyalties, conflicts in desires, differences in perspectives, and an unwillingness to openly share information can stymie the [process]."<sup>2</sup> For these reasons, it may be beneficial for a cross functional team made up of middle management and technical employees to carry out these tasks. The members should be from different departments and have varying skills in order that a comprehensive and broad scoped evaluation be performed. Some of the techniques presented rely heavily on input from departments other than manufacturing. Therefore, Process Engineering, Quality, Marketing, Sales, and Purchasing to name a few must help to define the projects up front. The methods presented help to overcome some of the inevitable organizational obstacles so that decisions can be made in a systematic fashion.

## **6.3 JUSTIFICATION**

It is difficult to argue why a company shouldn't optimize its resources. However, there may be argument over spending considerable time in identifying, analyzing, and prioritizing projects. Statements such as "Our problems are easy to

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<sup>2</sup>Souder, 1984 pg. 2

define, we just need to determine how to solve them" may be encountered.

However, spending up front time in this area helps an organization minimize the risks associated with improvement activities. A single improvement team may contain up to eight employees or more. Their efforts may consume 10%-50% of their time over six months to a year. The company would surely benefit by ensuring that this team, and others, spend this time wisely. In addition, these steps optimize the resources available. For example, they can prevent a situation from arising where the projects selected overburden the project team to a point where normal duties are sacrificed.

"Project selection decision makers frequently have much less information to evaluate candidate projects than they would wish. Uncertainties often surround the success likelihood of a project, the ultimate [benefit] of the project and its total cost to completion."<sup>3</sup> Therefore, it is critical that a systematic method be employed to reduce the risks associated with the improvement projects as well as to develop a common improvement perspective across the organization.

Juran<sup>4</sup> states: "An agreed upon project is also a legitimate project. This legitimacy puts the project on the official priority list. It helps to secure the needed budgets, facilities, and personnel. It also helps those guiding the project to secure attendance at scheduled meetings, to acquire requested data, to secure permission to conduct experiments [etc...]"<sup>5</sup>. Therefore, projects selected in a systematic way can more easily obtain the resources necessary for success.

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<sup>3</sup> Souder, 1984 pg 2.

<sup>4</sup> Juran 1988

<sup>5</sup> Juran, 1988, pg. 22.18-22.19



The Acme improvement initiatives could have greatly benefited from this up front analysis. The initial project identification step was performed. However, the effort involved proceeding directly from project identification to problem solving. A significant improvement opportunity was not pursued because its benefits were not readily apparent during the identification step. Later analyses revealed this opportunity. Up front analyses could have started work in this area 3 months earlier, thus providing the company with more months of potential benefits.

As described in chapter 2 the effort initially involved two cross functional teams assigned to improve printing quality and to increase Product B yields. These teams were formed with input from manufacturing, engineering, and research personnel which led management to assign team members based on the perceived root causes of the companies problems, printing defects and a specific step in the manufacture of Product B, Later analyses revealed that the root causes of tablet defects (the underlying reason for 100% inspection) went beyond the printing process step and into the coating process preceding it. The team assigned to the printing improvement project was limited by its skills (which were perfect for the perceived problem) and its ability to shift gears and go into the coating process.

#### **6.4 PROJECT IDENTIFICATION**

The first step in Level II of the methodology is to identify areas, processes, or products that have potential to meet the goals presented by upper management. For example, in the Acme initiative, the goals were to reduce cycle time by 50%, and reduce waste by \$3M. The task of middle management was then to determine what were the most significant areas of excessive cycle time and waste and assign projects to attack these areas.

### 6.4.1 Output

The result of this step in the process is to outline some broad areas that need to be analyzed to determine if they can be formed into viable improvement projects. In the Acme case, the areas brought forth were elimination of 100% inspection of tablet products and increasing the yields of product B, a capsule product filled with beads. In both of these cases, FDA regulations imposed severe constraints on allowable process changes and also tightly specified acceptable quality levels.

### 6.4.2 Techniques

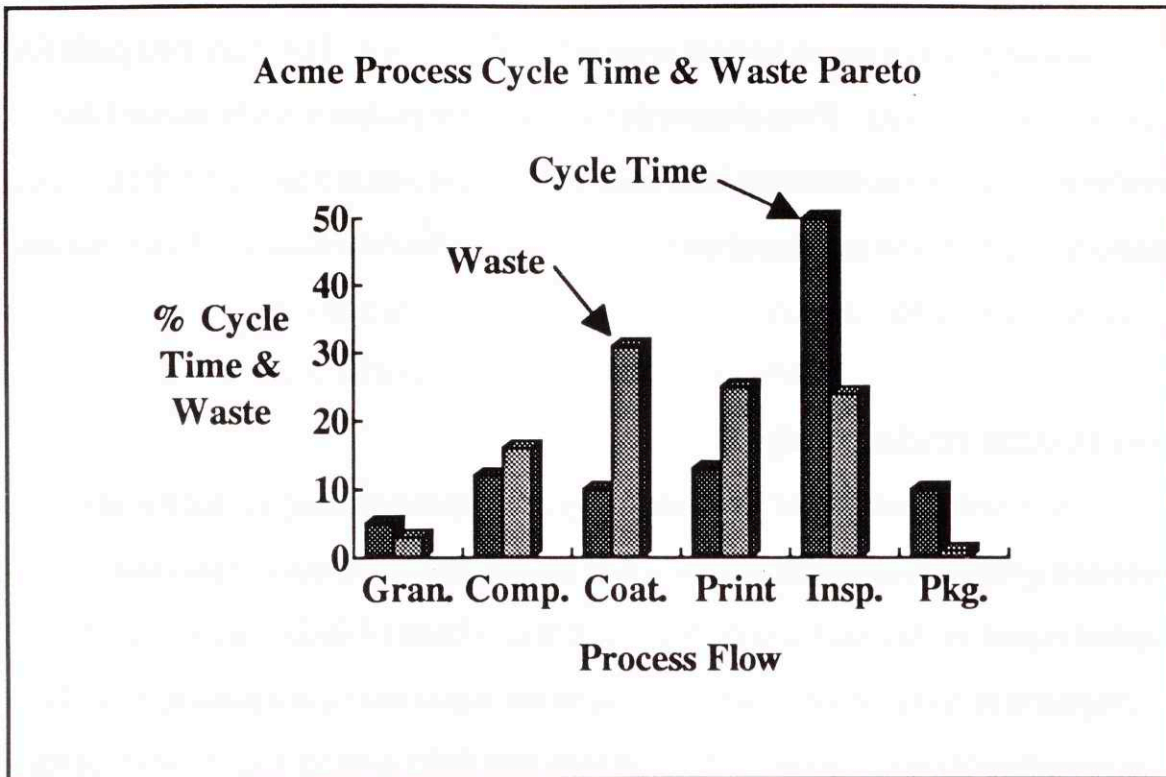
The main technique used by Acme was the Pareto chart. Juran<sup>6</sup> recommends this technique as a good initial step in project identification. The Pareto charts created by Acme were based on the goals of upper management. Thus the company compared different processes and products against these goals. For cycle time, they compared different processes to determine which areas caused the greatest components of overall cycle time (Figure 6.1).

Included in Figure 6.1 are the wastes associated with *tablet* products (as a percentage of total tablet waste). The data presented was broken down into the separate process steps during a later analysis. Waste out of inspection is defined as good tablets that were mistakenly rejected. Acme did not initially have the ability to discern waste (or defects) between coating, printing, and inspection. Therefore, during the initial Pareto analysis, waste appeared only inspection and without any further understanding of the process, Acme assigned this waste to the printing process. This became an important factor in selection and resource allocation for improvement projects. Section 6.5.1 will discuss the impact of this problem.

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<sup>6</sup> Juran, 1988

Figure 6.1



A similar process was performed for waste amounts for different products. As mentioned, two initiatives were then formed. The first consisted of a cross-functional team assigned to eliminate 100% inspection. The team consisted of operators and a supervisor from the printing process area, as well as QC and Engineering representatives familiar with printing technology. The second effort was also a cross functional team designated to improve the yield of Product B and contained operators, a supervisor, and research scientists familiar with a critical process steps for this product. On each, a selected manufacturing member was designated the team facilitator.

## **6.5 PROJECT ANALYSIS**

Project Analysis involves obtaining as much information as possible so that more detailed and concrete project proposals are obtained. There are two goals for this improvement step. First, a more detailed level of problem analyses must be performed on each of the areas identified in the previous step to ensure their viability. Second, the requirements for each project must be analyzed to determine if it can be executed.

### **6.5.1 Detailed Problem Analysis**

A detailed analysis of the initial project areas is necessary to distinguish between symptoms of problems and a first pass at the root causes of problems. A critical aspect of this work involves using data as a basis of decisions instead of perceptions or 'experience'. For example, in the Acme effort, the printing quality improvement team was formed with the idea that defects occurring in the printing process step (immediately before inspection) were the reasons that inspection was necessary. After much work by the team, no significant strides were made in reducing defects. There were still too many defects to justify eliminating 100% inspection and switching to sampled inspection. At this time a more detailed analysis was performed. This analysis revealed that a significant cause of defects was the process step immediately preceding printing (two process steps before inspection). This process was the coating process. As it turned out, coating defects were just as prevalent as printing defects. In addition, data revealed that there was a correlation between coating defects coming into printing and the level of printing defects exiting this step. Since the members of the inspection elimination team were either working in or familiar only with printing processes, they did not have the capability, authority, or time to attack defects occurring in coating as well as printing. Therefore another team was formed to tackle coating related defects; the

coating quality improvement team. When these two teams started to make changes to the process, significant strides were made in reducing defects.

To catch incidences such as above in the project development stage, the problem areas identified should be addressed along at least four analysis points; time, place, type, and symptom<sup>7</sup>. These will help to discover the features of the problems. They are not the only points that should be considered. The goal is to analyze the problems from as many different points of view as possible.

### **6.5.2 Project Requirements Analysis**

Assuming that a more detailed problem specification has been performed, another type of analysis must be done. This is to define the requirements needed to solve each problem. In addition, other factors such as risk and responsibilities as well as the organizational method for problem solving need to be addressed. Experts offer a wide range of potential reference areas from which to collect information. A sampling of these are: benefits, costs, risks, & ability to meet goals<sup>8</sup>; activities required, personnel and facilities needs, responsibilities, & time schedule<sup>9</sup>; rewards and recognition, communications requirements, measurements, & employee participation<sup>10</sup>; products effected, information technology needs, & skill requirements<sup>11</sup>.

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<sup>7</sup> Kume, 1985

<sup>8</sup> Souder, 1984

<sup>9</sup> Juran, 1988

<sup>10</sup> Kendrick, 1984

<sup>11</sup> Gunn, 1987

### **6.5.3 Output**

The outcome of the Project Analysis step are numerous viable improvement projects. These will be defined in such detail that they can be compared against each other in the Project Prioritization step. It is also possible that several projects may have been spawned from a single improvement area from the Project Identification step. For example, two projects to eliminate 100% inspection. In addition, some projects, or even improvement areas, may have been eliminated at this stage due to significant problems or through lack of sufficient information.

### **6.5.4 Techniques**

There are three techniques that were used in the inspection elimination effort which greatly improved knowledge on the problem. Use of these and other widely publicized methods in an up-front analysis would benefit improvement efforts.

#### **6.5.4.1 Fishbone (Ishikawa)**

A well known technique is the fishbone or Ishikawa diagram. It is a good technique for separating the potential causes of problems into five possible areas; processes, people, machines, environment, or input materials. This is a good starting point for a company. The fishbone allows potential causes to be broken down into possible areas. This will structure further analysis efforts into the five categories.

#### **6.5.4.2 Weighted Pareto Technique**

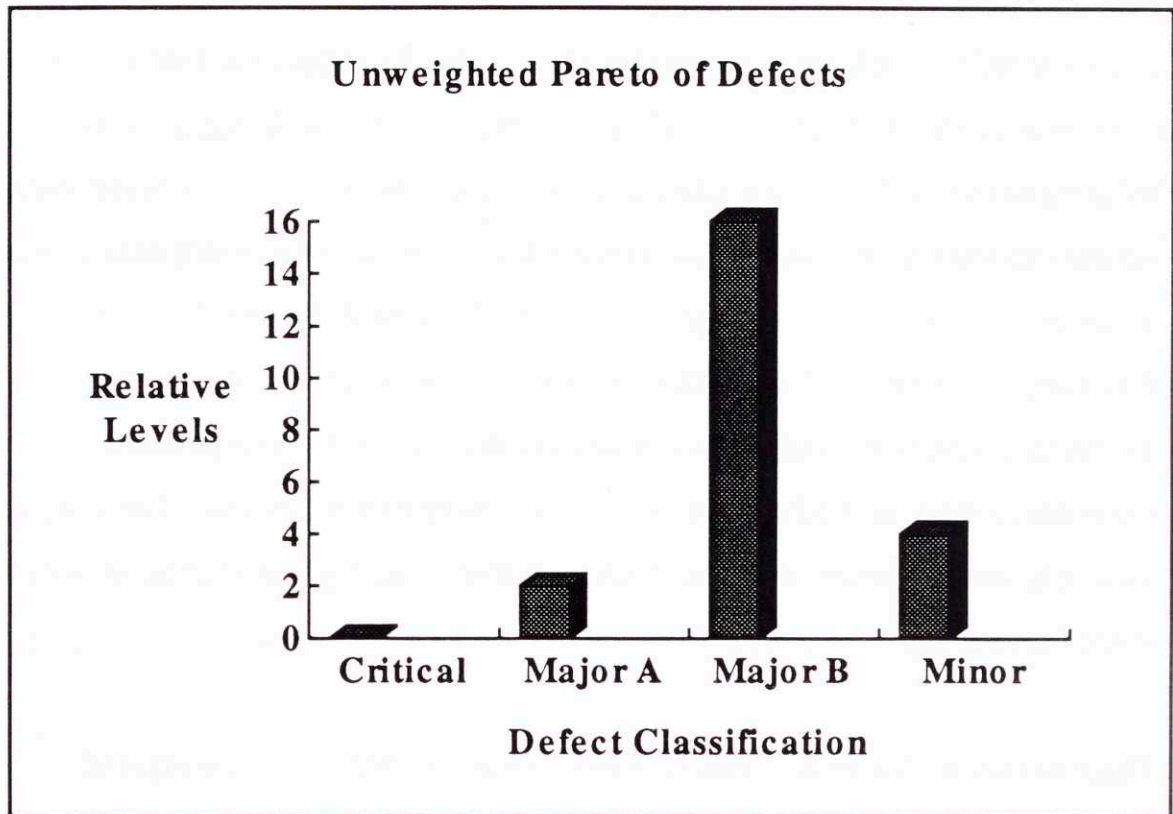
In the manufacture of drugs in tablet form, companies must submit to the FDA what quality control and inspection procedures it will use. A major component of this submission is the product defect classifications. The company

states that these defect classes must fall within acceptable quality levels (AQL's) before the drug will be packaged and shipped. AQL's are determined using samples of 200 tablets taken from product bins during production. There are different AQL's for different defect types. If any defect type in the sample occurs at a level above the AQL limit for that defect, then the bin that the sample was taken from must go through 100% inspection. Thus, as mentioned previously, significantly reducing defects will eliminate 100% inspection and allow sampled (the actual AQL sample) inspection. For instance, a broken tablet is considered a severe defect since it may provide an improper dosage to a patient. Thus the AQL for this defect states that a single broken tablet out of the 200 tablet sample results in 100% inspection of the bin to ensure that no other broken tablets exist. The AQL for a smeared but still readable print on a tablet allows up to 20 of these defects per 200 tablet sample since it is merely a cosmetic defect. Bins must continuously go through inspection, a visual process, and have defects removed until the AQL's are met.

There has been a lot written about the effectiveness of AQL's in the pursuit of quality improvement. The inspection elimination team did not intend to improve quality to just below the AQL level of each defect. The real way to eliminate inspection was to eliminate defects. However, the AQL's did provide a significant piece of information. They allowed the team to compare different defects against each other for severity. For example, an initial Pareto diagram of defect types entering inspection is shown in **Figure 6.2** (the data has been disguised for confidentiality). All defects (due to FDA submissions) are categorized into four areas; Critical defects which include foreign matter or batch contamination, Major A defect which include only broken tablets, Major B defects which include coating defects, illegible print, and unprinted tablets, and Minor defects which include ink

spots, double print, and smeared print. Each of these classes contains separate acceptable quality limits for samples taken during production.

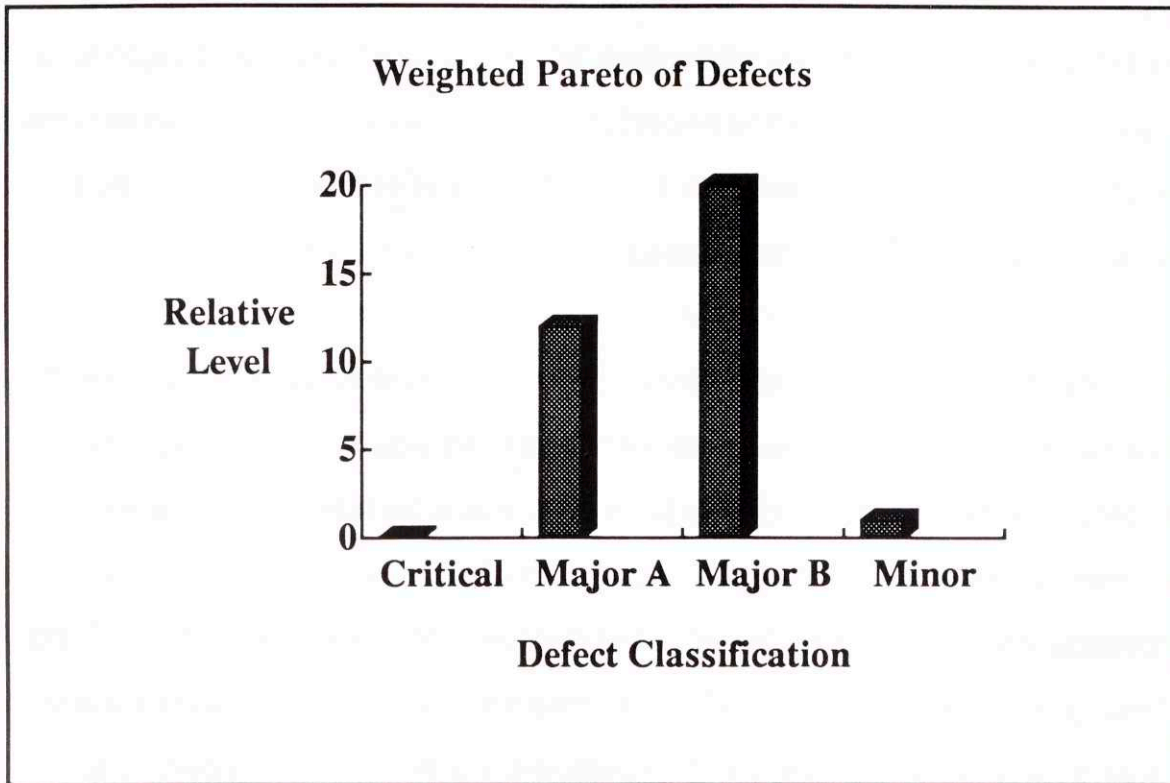
Figure 6.2



This technique leads one to believe that Major B defects are the most significant problem followed by Minor defects. However, this does not take into account the severity of the defects. To do this, a Weighted Pareto Technique was used. This involved multiplying the original Pareto values by a weighting factor which was obtained from the AQL levels. For example, broken tablet defects were weighed 10 times more heavily than smeared print tablets since their AQL's were 10 times more stringent. The result of this technique is the Pareto shown in Figure 6.3



Figure 6.3



Using this Pareto, the relative impact of defects is better known to the company. The technique can be applied in other improvement efforts by using information on the impact of defects. For instance, Marketing may have data on what the cost of different defects are in terms of lost sales, returns, or paperwork. An industrial plant may want to use rework costs, material costs, or lost machine overhead time. The end result will be a more clear picture of the relativness of defects for a particular manufacturing organization.

There can be numerous steps in this process. For example, the cost of repair for each defect type may 'weighed' into the Pareto results. Then the material waste costs could be 'weighed' in. In the pharmaceutical and other controlled industries,

the quality levels can be used. Each criteria that is used for comparison involves a separate weighting. It is important to realize that the end result of this technique will only be a *relative* measure of the items being compared. For specific questions regarding impact, the steps must be performed a separate activities so that integrity is not lost by confounding the data. For the purpose of process improvement, a relative measure is exactly what is needed.

It is important to chose weighting criteria based on the improvement task at hand. For example, in the Acme case, customer return cost was not inputted into the analysis. Although there may have been good reason for this input, it was not relevant to the improvement goals. If the goals stated that increased customer satisfaction was a key strategic goals, then this type of data would be used. For the Acme projects, elimination of 100% inspection was the goal. AQL's were the key criteria for deciding on when 100% inspection would be necessary, therefore the only weighting criteria were AQLs.

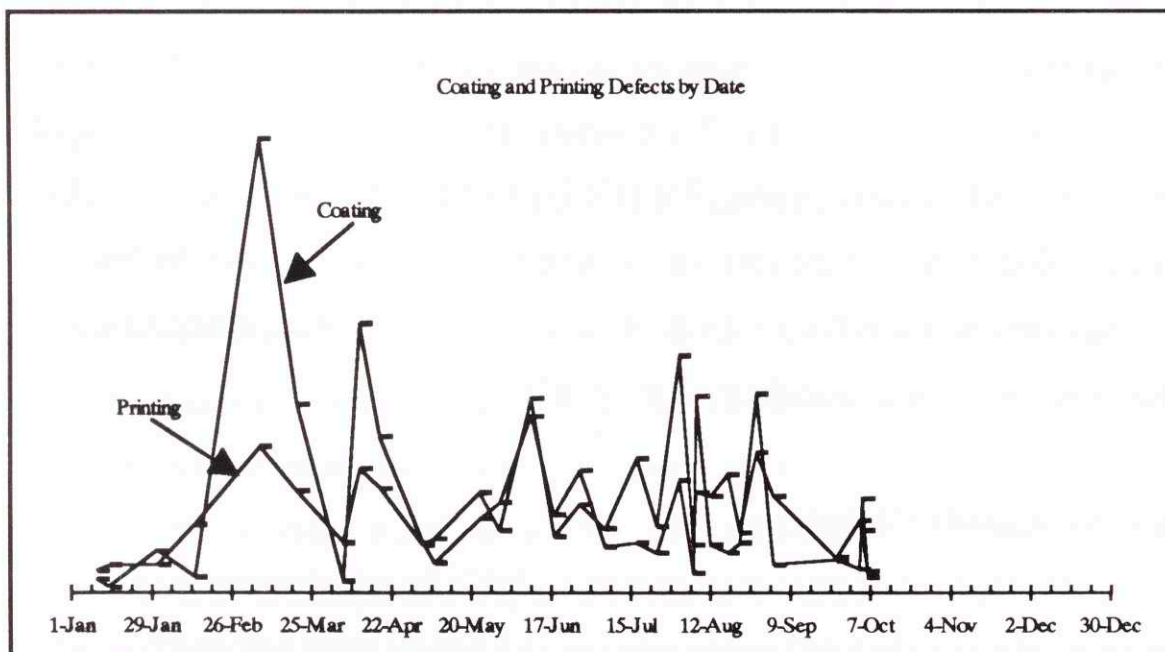
#### **6.5.4.3 First Level Root Cause Analysis**

The analysis that revealed the need to attack defects in the coating process was a first level root cause analysis. It was not performed up front because, traditionally, root cause analyses are reserved for problem solving efforts. However, in the Acme case, the benefits of using this technique at the project Level are revealed. The researcher, who was familiar with problem solving methods and who was not bounded by the organizational and pre-judgment thought patterns of the company, was able to take a step back and perform this analysis.

The technique used was fairly straight forward. A series of production batches were charted in terms of percentages and types of defects discovered in each. This chart,

shown in **Figure 6.4**, provided some insight into the interdependencies of the coating and printing processes. One can notice a correlation between defect levels just by the fact that all defects seem to rise together. In fact a correlation analysis revealed that the sample correlation factor was 0.44 (with a t-statistic over 22.0) between coating defects and all printing defects. Understanding of the processes brought the conclusion that coating defects (the preceding process) impacted the printing process. In more simple terms, defect created in coating caused more defects in the printing operation. The technical reason for this phenomena is that badly coated tablets have rough surfaces. Printing machines used for tablet printing rely heavily on tablets vibrating and flowing easily through the machine. Tablets with rough surfaces coming out of coating do not flow as nicely as ones with smooth surfaces. Therefore, the printing machines are not able to process these tablets with the same level of quality.

**FIGURE 6.4**



Recall that the researcher started with the team in the June time frame. A more complete graph of defects by date is provided for reference. The y-axis has been omitted for confidentiality.

## **6.6 PROJECT PRIORITIZATION**

Once project areas have been identified and analyzed, the next step is to prioritize these given the companies resources, skills, time frame, and confidences. The above Project Analysis is performed mainly to allow concrete decision making in this step. There are numerous systematic methods available to prioritize and select projects. A few of these fit well into the Multi-Level approach to process improvement. These will be described briefly to explain their contribution to process improvement.

### **6.6.1 Output**

The result of this process improvement step will be a clearly defined list of improvement projects that the company can execute in order to achieve the goals established by top management. The projects need not be presented as prioritized efforts to problem solving teams. The prioritization is performed in order to select those projects that optimize the resources of the company and achieve the best return on effort. Once these projects are selected, they can be implemented as the next wave of the continuous improvement cycle.

### **6.6.2 Prioritization Techniques**

There are many types of techniques available for selecting among numerous projects. Research in R&D project selection can provide some new insights. In this area, techniques such as decision trees and selection matrices can be of help. The following techniques have been presented and tested in actual process improvement

efforts. They would also fit well into the Multi-Level approach due to feature that will be addressed individually below.

### 6.6.2.1 Pareto Priority Index

Juran<sup>12</sup> recommend a simple and straight forward approach to prioritization of projects. This method is called the Pareto Priority Index (PPI). It involves developing an equation using variables important to the decision making process. For example, a company could prioritize based on cost (C), completion time (CT), savings (S), and probability of success (P(s)) by using a PPI such as:

$$\text{PPI} = [S \cdot P(s)] / [C \cdot CT]$$

In this case, a project with a high PPI would be preferred since it would have high savings and confidence with relatively low cost and completion time.

The equation can be manipulated to meet particular needs. If cost is a highly sensitive measure, then the equation can be modified to be more sensitive to this variable:

$$\text{PPI} = [S \cdot P(s)] / [(C^2) \cdot CT]$$

Likewise, other sensitivities as well as other variables can be added. Problems come into play when a variable can not be given a numerical value. In this case, it would be necessary to compare the project choices and rate them separately, perhaps on a 1-10 scale, on this one variable. Then the variable can be inserted into the PPI formula. It is important only to be consistent between projects.

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<sup>12</sup> Juran, 1988

### 6.6.2.2 Scaling Model

Souder<sup>13</sup> recommends a Scaling Model which develops a project priority score by ranking it on a number of important criteria (a sample ranking sheet is provided in Figure 6.5). In the Project Analysis step above, these criteria have already been analyzed. Therefore, the use of this model would fit well into the Multi-Level approach.

FIGURE 6.5

**SCALING MODEL EXAMPLE**

		SCALE				
		-2	-1	0	1	2
FUNCTION	CRITERIA					
	Top Mgmt					
	Capital Req'd					
	ROI					
	Comp. Benefits					
Engineering	Req'd Equipment					
	Avail. of Eng's					
	Design Difficulty					
Research	Patentability					
	Interactions					
	Stability					
Marketing	Product Advantage					
	Life Cycle Impact					
	Customer Reaction					
Production	Processability					
	Equip. Availability					
	Training					
	Support					
	Reliability					
	TOTAL	-2	-2	0	5	4

**TOTAL SCORE = 5**

<sup>13</sup> Souder, 1984

Once a ranking has been performed on the project, there is opportunity at this point to improve certain aspects of it. In the above example, there is a low score for availability of engineers but the project has a very good ROI. Perhaps the ROI is so good that extra engineering support may be added without reducing the ROI from a 2 to 1 score and allowing the availability of engineers score to move up. This type of manipulation is possible with this technique but it may not be the most appropriate. A better way to account for the importance of each criteria would be to add weights to them. This technique along with a few other modification is used in the Weighted Scoring Matrix described later.

### 6.6.2.3 Harris Model




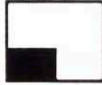



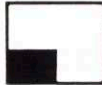









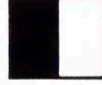
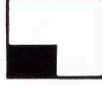
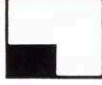
Harris<sup>14</sup> proposes a method similar to the Scaling Method. His method also ranks projects on a scale (in his case 1-4) for various important decision criteria but ranks these in a simple to view matrix fashion. An example is show in **Figure 6.6**. The advantage of this model is the ability to view all the projects at once and get a visual feel for each. It is recommended that the ranks for each decision criteria be obtained from averaging individual ranks from affected personnel such as plant operations, vendors, and quality control to name a few.

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<sup>14</sup> Harris, 1990

**FIGURE 6.6**

**Harris Prioritization Model**

CITERIA	Project A	Project B	Project C	Project D
Impact				
"Do-ability"				
Timing/Finish				
Fit				
Customer				

The drawback to this model is that the visual simplicity loses its benefit when many criteria and/or projects are compared. In addition, it can get difficult to distinguish projects when the scale is increased from say 1-4 to 1-8. In these cases, it would be necessary to regress back to the numbers instead of the visual pies/blocks.

#### 6.6.2.4 Weighted Scaling Matrix

A method that combines many of the benefits of the above techniques is proposed. This technique is called the Weighted Scaling Matrix. It is very similar to the Concept Selection Matrix proposed for choosing among various designs in the development of new or improved *products*<sup>15</sup>. The benefits of this technique are the

<sup>15</sup> Howlett, Ulrich, & Eppinger, 1991



ability to evaluate projects along multiple criteria, develop a single project 'score', use data driven *and* judgment driven criteria, and finally weight decision criteria differently.

**Figure 6.7** shows a weighted scaling matrix for potential choices for Acme (This method was not performed during the study but is included as a detailed example). Project A was designed to eliminate printing of tablets entirely and redesign the product to have its name embossed during tablet formation. Project B was a proposal to install automated inspection systems to speed up the 100% inspection task and reduce the variability associated with human inspection. Project C and D are the elimination of 100% inspection and product B improvement projects, respectively.

The first step of the technique would be to determine the comparison criteria and the relative importance of these criteria for the company. Then the projects should be ranked for each of these criteria. In the Multi-Level approach, the criteria and some form of measurement or ranking has already been performed before reaching the prioritization stage. However, the criteria weighting still needs to be performed. It is suggested that these weightings be performed after the criteria are entered into the matrix but before the rankings or projects are inserted. This will prevent any biasing of weights based on certain projects. It is important that the weights also be connected to the improvement goals presented by upper management.

There will also be a need to convert hard numbers such as cost savings into a rank and possibly an evaluation criteria such as waste reduction at this point. For instance, project A could have provided a cost savings of \$2M through eliminating the printing process and its associated cycle time and waste. This would have been

considered a significant benefit for the company, therefore this project will receive a +1 rank for waste reduction as well as a +2 for cycle time reduction (it is assumed that these evaluation criteria were determined in advance of the ranking) Also, for this project, say the confidence of success is very low due to the uncertainty of being able to design an embossed tablet. This would be considered a very significant negative benefit. If there is a very negative impact, it will get a -2 ranking. It is also uncertain whether overall quality will improve or decline. Therefore, projects with many positive numbers are preferable since they will lead to a high positive end score.

Once all the weights have been established and the projects ranked along the evaluation criteria, the overall project scores (S) can be obtained the sum of the ranks (R) times the criteria weights (W):  $(S = \sum_i (R_i * W_i))$  These scores are shown at the bottom of the matrix in **Figure 6.7**. In this example the projects will be prioritized as project D being the most preferred, followed in order by C, A, and B. Projects D, C, and A would be considered as potential viable projects given the resources and capital available. Project B would not be considered a viable project and would be dropped from the list.

**FIGURE 6.7**

**Weighted Scaling Matrix Example**

Evaluation Criteria	Weight	Project			
		A	B	C	D
Waste Reduction	3	1	1	1	2
Cycle Time Reduction	3	2	1	2	0
Quality Improvement	2	0	0	2	2
Variability Reduction	3	1	0	1	1
Customer Impact	1	1	0	1	0
Resources Needed	2	-1	-1	1	1
Time to Complete	1	0	-1	0	-1
Risk	2	-2	-1	0	1
Cost	4	1	-2	0	1
<b>TOTAL SCORE</b>		<b>11</b>	<b>-9</b>	<b>19</b>	<b>20</b>

Once the projects have been prioritized, it must be determined how many projects the company can implement due to budget and resource constraints. This may be accomplished by progressing through the prioritized list and assigning resources as defined in the Project Analysis step. When either personnel or budgets are used up, the selected projects are thus defined and are ready for execution. This assumes that the non-viable projects have been removed from the list of candidates.

## 6.7 CONCLUSION

The Project Identification, Analysis, and Prioritization steps will provide a firm with techniques and motivation to optimize its process improvement activities. The Acme case study gives justification for these methods as well as descriptions of some of them in practice. Significant further benefits could have been possible at Acme with the implementation of these three steps in the improvement process. The projects would have been chosen accordingly up front, and thus staffed with appropriate personnel and provided the needed direction and resources. It is estimated that approximately three months could have been saved simply by selecting the appropriate projects up front. The dollar savings from this optimization is estimated at approximately \$500K.

The methods described are not intended to be a single pass process. The goal is to get middle management as well as engineering and operational personnel to work together and understand the companies processes as well as to make educated decisions on the organizations courses of action. This can only be facilitated through open communication and knowledge transfer across organizational boundaries. Other factors which can hinder the process are the lack of data on how the company is doing *now*. Optimal projects decisions can only be made through cross functional input and through complete knowledge of the current state of operations.

Inevitable future passes through the phased improvement cycle and subsequently through these three improvement steps brings up another point to consider. This is one of project analysis and comparison consistency. If the company spends some time up front to determine how projects should always be measured and compared, then further improvement cycles can benefit from past ones. For example, a project which was not chosen in a current cycle may become viable in the next improvement

cycle. Much work will be saved if the techniques, analyses, measurements, and comparisons are kept similar as well as thoroughly documented. Obviously, if there is good reason to change a technique then it should be done. However, a major benefit of systematic improvement methods is that these should be minimal. Thus allowing past efforts to be helpful in the future. This is also a major argument for sticking with a consistent methodology and not progressing from 'program' to 'program'.

## 7. Discussion

The methodologies presented in this research serve to promote systematic improvement of operations. The goal is to achieve strategically beneficial results while optimizing the resources available. This work and that of McDonald<sup>1</sup> provide a framework in which a system can be put in place to constantly achieve improvement. It is important that the methodologies be used with full commitment. Otherwise, the techniques will be cast aside whenever complications occur. Relegating the methodology as another directive in an indecisive environment. The author hopes that further modifications are made to this effort so that issues can be addressed in more depth. Although every effort has been made to provide a general process improvement methodology, there will be inevitable fine tuning in order that the techniques better fit the organization. Hopefully, these modifications will build upon the benefits of the research and not diminish its potential.

Two key underlying aspects of the Multi-Level methodology need to be mentioned. First, this process is a top down method of promoting improvement. It does not rely on the assumption that empowering workers will enable improvement to take place. Improvement can take place by empowering 'lower' levels of the organization, but will these improvements be strategically beneficial? Second, Level II of the methodology assumes that middle level management and senior technical staff are aware of and understand the manufacturing processes in their organization. Without this knowledge, the activities in Level II may not be feasible. This is an intentional aspect of the methodology.

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<sup>1</sup> McDonald, 1992

This thesis focuses on the development of the Superset and Multi-Level methodologies and goes into specific detail on Level II of the Multi-Level Method. McDonald<sup>2</sup> provides greater depth into Level III of the Multi-Level method. There are many areas where further research is required. Level I of the Multi-Level method is not addressed in-depth. The information available during the Acme case study only provided limited ability for in-depth coverage in this area. More work is also needed in areas of communication between levels and in multiple improvement project management and direction. For instance, what are the necessary support roles for upper and middle management? Can current project management methods be used within the framework of the Multi-Level? Another potential area of research involves the use of the Multi-Level approach in companies of differing size. Is the approach valid for very large as well as very small companies? If not, what changes may be needed to accommodate these organizations. Finally, the implementation of systematic methods needs attention. How does one get such a far reaching methodology implemented with complete acceptance, support, and involvement in an organization?

There have been questions as to whether the Multi-Level approach is valid for fire fighting activities. Fire fighting can be considered a Level III activity; most of the work is in the problem solving realm. Therefore, the techniques in Level III may provide benefit for fire fighting. It can be assumed that the problem is readily identified and that it is of high priority. These components of Level II are already addressed at this point in the situation. However, a key aspect of the Multi-Level approach will have been left out. This is the Project Analysis step of Level II. Here is where a first pass root cause analysis is performed and where the requirements to

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<sup>2</sup> McDonald, 1992

solve the problem are analyzed. Without this effort, problem solving can still occur, but it must be accepted that there may be difficulty in determining the root cause of the problem if it is not within the scope of those assigned to the problem. In addition, there may be inefficiencies involved in allocating resources to the problem. Too few resources will slow resolution. Too many resources bring about opportunity costs as well as lower marginal productivity. Further work is needed to determine if Problem Analysis can occur as an independent fire fighting initiation activity.

The use of a single case study, although very intensive, brings up issues of transferability into other organizations. Specific organization specific actions may have skewed the results. Therefore, the author is continuing to study this topic as a member of another division within Acme company. Hopefully this work will help to fill this gap.



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