A Data Driven Approach to Quality Assurance, Continuous Improvement, and Learning

By

Andra Sloane Weissberg

BS., Chemical Engineering
Rensselaer Polytechnic Institute (1984)

Submitted to the Alfred P. Sloan School of Management and
the Department of Chemical Engineering
in Partial Fulfillment of the Requirements for the Degrees of

Master of Science in Management
and
Master of Science in Chemical Engineering

In conjunction with the Leaders for Manufacturing Program
at the
Massachusetts Institute of Technology
May 1994

Signature of the Author ______________________________
Department of Chemical Engineering
MIT Sloan School of Management
May 6, 1994

Certified by ______________________________
George Stepanopoulos, Professor, Department of Chemical Engineering
Thesis Supervisor

Certified by ______________________________
Roy E. Welsch, Professor, MIT Sloan School of Management
Thesis Supervisor

Accepted by ______________________________
Jeffrey A. Barks, Associate Dean of the Sloan School of Management

A Data Driven Approach to Quality Assurance, Continuous Improvement, and Learning

By
Andra Sloane Weissberg

Submitted to the Sloan School of Management and the Department of Chemical Engineering in Partial Fulfilment of the Requirments for the Degrees of

Master of Science in Management, and
Master of Science in Chemical Engineering

Abstract

In today's competitive environment, corporations are placing heavy emphasis on improving the product delivery process and the quality of each new product introduced. The Helios System, a new imaging system, incorporates a greater variety of technologies working together than traditional photographic systems. It involves the complex integration of mechanical and electrical hardware, computer software, optics, and film media. The change that has allowed Polaroid to leverage these components into a highly complex system calls for a dramatic transformation in the processes used to manufacture and assure the quality and continuous improvement of product.

The primary consideration for developing a data-driven approach to quality is to assure that Polaroid is continually meeting or exceeding customer's expectations as well as that of outside regulatory or certifying organizations. The need for a formal system is even more critical because the media manufacturing organization has to share valid data with group members from different technical disciplines and organizational functions. For this information to be useful, it must be accurate and accessible to all individuals on the cross-functional team to make management or technical decisions.

Throughout this project, I have emphasized the need for methodologies to learn from historic production and quality data. Our results provide guidelines to manufacturing for data collection and data organization methods; including tools for identification of what data is needed for process analysis. We evaluated various data analysis techniques and tools, namely univariate and multivariate diagnostics, and classification decision trees, to use to identify the factors impacting systems performance and manufacturing variability. Finally, we employed Design of Experiments to confirm our findings and verify or expand the safe zones of operation.

I integrated the learning from this research effort into a systematic approach to quality assurance and also to serve as a guide for future product and process improvement efforts. We were able to incorporate this knowledge into the development of a new media prototype that was recently released for customer use. I conclude with recommendations for areas of future study that should help further improve the overall product delivery process.

Advisors:	Robert Pusateri, Rick Tino; Polaroid Corporation
	George Stephanopoulos, Professor, Department of Chemical Engineering
	Roy E. Welsch, Professor, MIT Sloan School of Management

Acknowledgments

I would like to thank all the people at Polaroid who welcomed me with such enthusiasm and encouragement. Special thanks go to my advisors, Bob Pusateri and Rick Tino at Polaroid, George Stephanopoulos and Roy Welsch at MIT for their support and guidance.

Many people at Polaroid provided tremendous assistance and resources: Henry Gale, Jack Goshtigian, Gil Friberg, Bob Dondero, Bob Wohler, Sue Richardson, Larry Yorell, and the rest of the High Resolution Media Manufacturing team at Norwood; Joe Stella, Andy Didanoto, Karen Freeman, Bud Rolfs and the rest of the Hardware Manufacturing and Reliability Engineering team at Newton, and the High Resolution Imaging Development team at Waltham.

I gratefully acknowledge the support and resources made available to me through the Leaders for Manufacturing Program, a partnership between MIT and major US manufacturing companies.

I want to thank my friends from the LFM program and the Sloan School who provided advice and encouragement during this process. My friends from home (Connecticut and Washington, DC.) also added their support and occasionally came to town to enjoy the sites of Boston.

Finally, my deepest appreciation to my family (Mom, Dad, and Michele) and my boyfriend Steve, for their enduring love, support, and encouragement during this experience.

Table of Contents

List of Figures

List of Tables

1. Introduction

In 1993, Polaroid announced the reorganization of the company into three major lines of business: Photography and video tape products, High Resolution Imaging, and future Electronic-imaging systems. Today, instant photography products account for 85% of Polaroid's revenue and almost 100% of the profits. The recent introduction of the Captiva camera, the result of a multi-year cross functional design effort, has been a called a "snappy success" by Business Week[1]. It was one of the hottest selling photographic items for the fall of 1993. Still, I. MacAllister "Mac" Booth, Polaroid's President, Chairman, and Chief Executive Officer, acknowledges that the company's future no longer lies in instant photography. "We plan to maintain our leadership role in photographic imaging and we intend to be fully established in high resolution imaging and electronic imaging systems by the end of the decade."[2] That is why the firm has used the profits from photography products as well as from the patent infringement settlement with Kodak to fund development efforts in high resolution imaging systems. Initially, Polaroid has exploited its expertise in coating, chemistry and electronics and set its sights on the medical imaging marketplace. The new Helios Laser Imaging System is a key part of Booth's strategy.

With the introduction of the Helios 810 Laser Imaging System in March of 1993, Polaroid entered the medical hard copy imaging marketplace with a dry processing system that eliminates the needs for chemicals, film processors, and darkrooms. The Helios system combines high resolution laser imaging with a carbon based laser film to provide high image quality and consistency in radiographic applications. The medical hard copy imaging arena is highly competitive and companies like Polaroid, 3M, Kodak, Fuji, and others vie for customers based on image quality, cost effectiveness, system reliability, and

---

[1] Gary McWilliams, "A Radical Shift in Focus for Polarod", Business Week, 26 July 1993,: 66.

[2] I. M. Booth, "Remarks from Chairman of Board", Polaroid Corporation 1993 Annual Report: 3.

system size. As in conventional photography, the consumable film market is where all the money is. "The Film market is definitely a driver for laser imagers. Hospitals buy large quantities every years worth millions of dollars in multi-year contracts."[3] said Mr. Neary of Fuji Systems.

1.1. The Laser Imaging System

The laser imager has been an important component of the radiography system since the mid 1980's. By 1995, experts expect the marketplace to grow to almost 20,000 installed units. The 3M Company, the first to introduce a laser imager, has the most installed units with over 6,000 worldwide. The laser imager also known as the laser printer produces images it receives from nuclear medicine, ultrasound, MRI, CT, or Xray systems. The imager creates a hard copy of a digital image from these radiographic systems in record time, reliability, capacity, and quality. Most systems on the marketplace use a solid-state laser diode to supply light in the near-infrared spectrum to expose silver-halide based film. The film is exposed on a pixel by pixel basis corresponding to the binary information from the radiography system. The exposed silver-halide film is then processed in a second step to make the actual hard copy.

The users -- radiologists and technologists, have found the quality of laser imagers superior to that of the older CRT (cathode-ray tube) based cameras. The laser imagers have a bigger dynamic range of film-image densities than older CRT based cameras, producing a maximum dynamic range of greater than 2.4 units and up to 3 or greater. In essence, the blacks are blacker and it makes the film easier to read. Laser imagers are also faster, with the fastest producing up to 300 images per hour. They have the ability to

---

[3] "Laser Imaging Systems", Second Source Imaging: The Medical Imaging Equipment Magazine, July 1993

store the digitized image for later use and serve as a printer for more than one radiographic system at a time.

1.2. Polaroid's Competitive Advantage

While the Helios 810 Laser System might be a "late entrant" in the laser imaging marketplace, it was the result of five years of effort by a multi-disciplinary team of Polaroid researchers, engineers, and marketing professionals. The goal was to develop the most convenient and highest performance hard-copy imaging system for diagnostic radiology that requires no wet chemistry. Competitive systems need a separate processor attached to the imager to process the exposed silver-halide film. The requirement to develop the film in a chemical bath can introduce a source of variability in the image quality. The user is also responsible for disposing of the chemicals, which are considered toxic and are strictly regulated in most states. In addition, the silver-halide film requires special handling and storage.

The Helios System uses a proprietary carbon based film which is very stable and requires no special handling. The film's imaging layer is activated by the system's high powered lasers. The system produces a hard-copy in ninety seconds, without the need for wet processing. The burden of disposing of any chemical waste is borne by Polaroid during the manufacturing of the film rather than the user. The user receives an image that is precise and sharp and indistinguishable from conventional single emulsion silver halide films. "Competitors acknowledge that if Polaroid succeeds with the Helios system, this dry film process could take laser imaging evolution off the map".[4]

---

[4] Ibid

1.3. Integration of complex new technology

The medical laser imaging application has a number of characteristics that are different from the traditional consumer markets Polaroid competes in. These imaging systems must be available seven days a weeks and capable of printing over a hundred images a day. The product is used by professional users that are very concerned about image quality and consistency. The Helios system incorporates a greater variety of technologies working together than traditional photographic systems. It involves the complex integration of mechanical and electrical hardware, computer software, optics, and film media. The technological changes that have allowed Polaroid to leverage these components into a highly complex system calls for a dramatic change in the processes used to manufacture and assure the quality and continuous improvement of product.

The successful manufacturing and delivery of the Helios system require effective integration of diverse technologies and people from different technical disciplines and organizational functions. The Helios development and manufacturing efforts draws on the skills and resources of over six plants and laboratories in five different geographic locations in the greater Boston area. Providing the customer's with a highly reliable and available system requires the effective management of the quality assurance process, also called the manufacturing release process, across these various organizations. It is not possible to meet the customer's requirements and expectations for system performance by optimizing and assuring the performance and quality of each component in isolation.

In order to meet this challenge, the High Resolution imaging group is relying on a more horizontal organizational structure to allow the employees to respond quickly to customer requirements. Each of the six or so sites has a particular set of manufacturing capabilities, development interests, and other expertise. They must continually cooperate and collaborate to ensure that the end result continually meets the customer's expectations. The program manager, a director in High Resolution Imaging, has the overall responsibility of ensuring that the product meets the customer's requirements as well as the company's goals for market penetration and profit. While none of the development, manufacturing, marketing or service groups report directly to the project manager, he coordinates the efforts across these organizations

One task is to get the marketing, service, hardware, software, and film group to talk to each other and work as an integrated team. While the firm has not moved completely to "self managed teams," there are some common set of performance objectives and measurements that the overall cross-functional team can work toward. For the Helios 810 System, this was facilitated by the introduction of a number of overall system performance objectives like improving or maintaining overall reliability, availability, and image consistency. In order to hold the team accountable for measurable performance goals, it is necessary to understand how the quality and performance of each component of the system, like media, can effect overall system performance.

At a more fundamental level, it is critical to have an understanding of how each input into the media manufacturing processes or other component manufacturing processes can ultimately affect the overall performance of the Helios system. When this understanding is achieved, the media manufacturing group or other component manufacturing groups can implement process or product changes that reduce variability and improve the robustness of each component manufacturing process. This may involve a change in the media, the hardware, or a combination of changes in the overall system. These actions will in turn improve the overall robustness and reliability of the Helios system.

1.4. Motivations for Developing Management Processes to Assure Quality

The primary consideration for developing and implementing a manufacturing release system is to ensure that Polaroid is continually meeting or exceeding customer expectations. Shoji Shiba, quality guru and professor at Tsukuba University (Tokyo) and MIT (Cambridge, MA) suggests that "Total Quality Management is an evolving system of practices, tools, and training methods for management companies to provide customer satisfaction in a rapidly changing world. TQM improves the performance in several areas: eliminating product defects, enhancing attractiveness of product design, speeding service deliver, and reducing cost among others[5]." If our system is to be able to help drive continuous improvement, it must be part of an organizational learning strategy like Polaroid's Total Quality process, rather than just a quantitative method of analyzing data. Therefore, a formal management process is required because:

- The organization that can learn more rapidly from its experiences and use that learning to enhance its performance will have a distinct competitive advantage.

- The Helios System is complex and quality must be viewed at a system wide level. Additionally, the system is highly interactive and this is quite different from traditional camera products.

- There is a need for formal management processes to comply with the certifying organizations and government regulations.

---

[5] Shoji Shiba, et. al. A New American TQM: Four Practical Revolutions in Management. (Productivity Press, Cambridge, MA. 1993)

There are a number of existing manufacturing release frameworks that can be employed to measure, affirm and improve the overall quality of the Helios System. Within Polaroid, the company has developed and implemented an overall Total Quality Ownership (TQO) program to create a focus on the requirements of the customer based on five main principles:

- Know your customers
- Meet then exceed their requirements
- Continually improve
- Innovate
- Participate as an employee owner

It has our intent to develop a management system to assure quality and release product that is built upon these TQO principles adopted by Polaroid.

1.4.1. Compliance with Government Agencies or Certifying Organizations

As a Class One medical device, the Helios 810 Imaging System also comes under the regulation of the Federal Drug Administration (FDA). The FDA has a set of requirements for Good Manufacturing Processes (GMP) that might be interpreted as a management framework to assure quality. The FDA GMP dictates that each supplier of a device complete a set of activities necessary to assure and verify confidence in the quality of the process used to manufacture that finished device.

In addition, Polaroid also seeks ISO 9000 certification for the media manufacturing plant. They have already obtained ISO 9001 certification for the hardware/software manufacturing facilities. The ISO 9000 series is a set of standards that were developed during the 1980s by the International Organization for Standardization to establish basic, uniform requirements for manufacturing release systems. They consist of a set of procedures that must be implemented by most US. companies wishing to do business internationally. The ISO 9000 standards do not refer to products and services, but to systems that produce them. The standards are designed to give buyers confidence that registered companies will consistently deliver what the buyer expects.

By itself, ISO9001 certification is not a stamp of quality. It only requires that a company have a defined process for delivering its product to customers and meeting any contractual obligations that may be required. However, in the processing of documenting everything you do that affects the design, production and quality of the goods and services produced, the firm has opportunities to eliminate waste and redundancy.

1.4.2. The Value of Accurate Information in Assuring Quality

The value of developing and implementing management processes to assure compliance with the FDA GMP or to meet the ISO 9000 certification requirements is that these management processes serve an integral part in a Total Quality Ownership program. To be effective, management and team members require the use of accurate information on all aspects of material flow, manufacturing processes, and quality testing. The review of good quality or accurate information is necessary to assure product quality and to make better business decisions. If the information is missing or of poor quality, then management by fact becomes very difficult and a lot of time and energy is wasted on internal information thrashing. This could result in producing unfavorable product/inventory, unnecessary overhead costs, and poor time to market based performance.

1.4.3. Objectives for our Manufacturing release System

The Management Release System or Manufacturing release system will integrate information from process control measurements, product evaluation measurements, and

System Performance measurements to assess product quality *(see Figure 1.1. below)*. To assist in this effort there needs to be a mechanism in place to continually update and refresh this information --- the firm's management and information systems should be reorganized for customer satisfaction. The need for this system is even more critical because the media manufacturing organization has to share valid data with group members from different technical disciplines and organizational functions. For this information to be useful, it must be accurate and accessible to all individuals on the cross-functional team that need facts to make management or technical decisions.

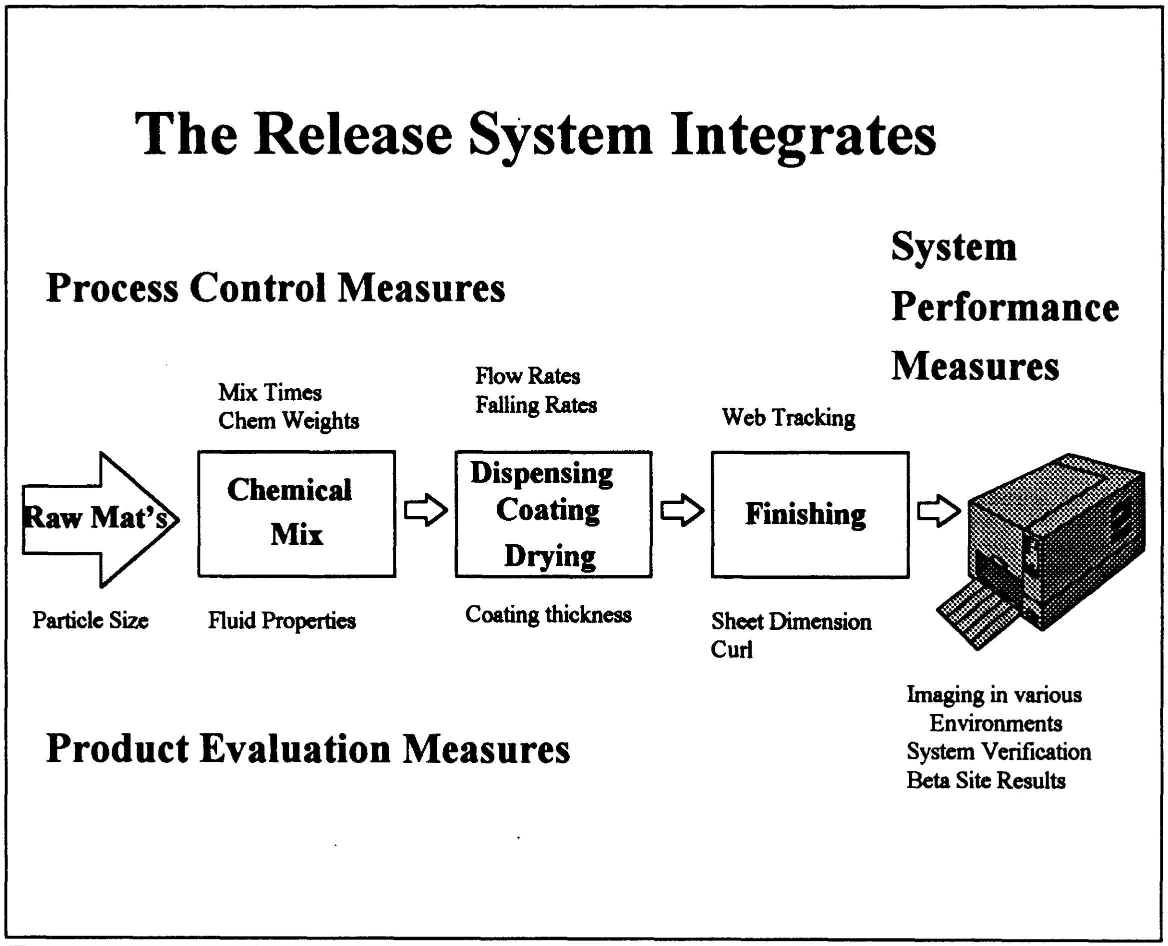


Figure 1.1: Manufacturing Release System Integrates Process, Product, and System Measures

We decided on a two-pronged attack. First, the team perceived value in creating a historic database which contained all the measurement variables for each case run since November of 1992. The data for each case would be stored in a number of relational database tables Second, there also must be an understanding of how these measurements of variables such as of raw materials properties, components, or inputs to the manufacturing processes affect overall Helios Systems performance. Only when these two objectives are achieved can the information from these areas can be used to release the product or continuously improve the quality of the product and processes.

1.5. The Nature of this Thesis

This thesis is based on a six plus month internship sponsored by the Leaders for Manufacturing Program at MIT. I conducted research at the Polaroid Norwood Sesame manufacturing facility, the site of media development and low-volume manufacturing for the Helios 810 System. The Helios System was brand new to the marketplace at the start of this internship experience, and the challenges of scaling-up manufacturing and supporting Helios Systems for a large number customers were new. As the first product from the High Resolution Imaging group, it was critical for Polaroid that the Helios 810 System have a successful product debut. Team members from all technical and management disciplines were dedicated to its success.

In the face of these challenges, the Norwood management recognized the need for a set of management processes to ensure that the product continually meets the customer's requirements. Because the product was the result of the integration of complex technologies and disciplines, the management processes had to take into account the dynamic nature of the product. The roll-out of the Helios System was proceeding at a rapid pace and a tremendous amount of change, learning, and growing needed to take place. This author feels very fortunate to play a role in this exciting product launch and the ongoing effort help to make customer satisfaction with the product high.

1.5.1. Thesis Roadmap

During the internship, I studied and experimented with methods for selecting, gathering and analyzing operating information necessary to assure quality of the film media. The objective was to be able to use this information to make better management and technical decisions to continually improve the product and processes. Three major phases of research activities provided the vehicles to examine these areas of interest:

- The development, and implementation of relationships between process, quality, and system measurements through a relational data base to provide a repository for accurate operational information.

- The use of statistical tools and modeling techniques on the operational information to uncover the predictive structure of problem. - that is uncover what variables or interactions of variables might effect the performance of the media in the Helios System.

- The deployment and communication of this information and analysis to members of the cross-functional team enable better management and technical decisions such as:
    - the more accurate assessment of the performance or quality of the product in the field;

    - the reduction of the sources of variability in the manufacturing processes; and

- the redesign of the media prototype to improve the robustness of the overall system performance.

This thesis follows the plan illustrated in Figure 1.2. Chapter 2 sets the stage and provides the reader with an overview of the manufacturing environment and the system complexity. The subsequent chapters address the three main areas of research as described above. A conclusion then summarizes the findings and recommendations. The overall guiding framework in this research process was Polaroid's Total Quality Ownership principles which helps provide and environment for organizational learning and continuous improvement.

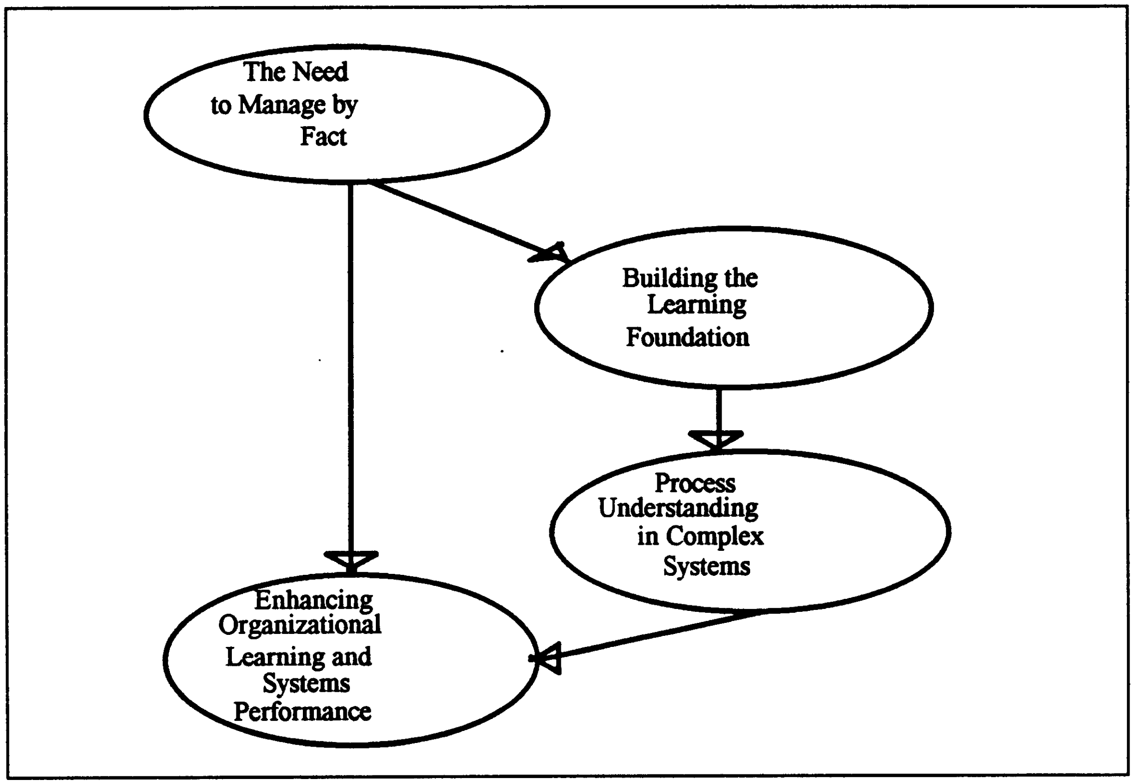


Figure 1.2: Thesis Roadmap

2. The Need to Manage by Fact

This chapter provides a context for the research performed by describing the manufacturing and development environments and potential sources of operating data for the Helios 810 Laser System within Polaroid prior to the start of the author's internship. It also describes, as necessary, the function of the hardware, software, and media required to produce a high quality image to meet customer requirements.

2.1. Laser Imaging as a Highly Interactive System

The Helios Laser System is the size of a large desktop copier. It is made to fit into a number of different environments in a hospital or clinic that might house radiographic equipment, office equipment, or staff. Many of these areas do not have special heating or cooling systems. Therefore the Helios System must be able to function well in a wide range of environmental conditions -- in room temperature or environments that are hot and dry, hot and wet, etc. The film media, packaged in sealed trays of 100 sheets, must also be able to withstand this variation of environmental conditions and still function properly within the Laser System.

To accomplish this result, Polaroid drew heavily on its knowledge of chemistry and coating as well as microelectronics, lasers and electro-mechanics. While the actual creation of a pixel is accomplished by the interaction of a high power laser with the carbon-based film, the system has a number of other electrical, mechanical and chemical interdependencies required to produce a finished image.

Unlike conventional silver halide based imaging systems, the Helios imaging mechanism of the film is highly deterministic. The film contains three basic layers. A uniform layer of a thermally activatable material (B) is covered by an imaging layer consisting of carbon particles embedded in a polymeric matrix. The carbon layer (CB) is covered by a thin release layer (K) comprised of a waxy or resinous material. These key layers, along with a number of other layers situated above or below this sandwich, improve the handling or mechanical properties of the media are placed between two polyester substrates (*see Figure 2.1.)*. The carbon particles of the imaging layer have a narrow size distribution between 50 and 100 A.

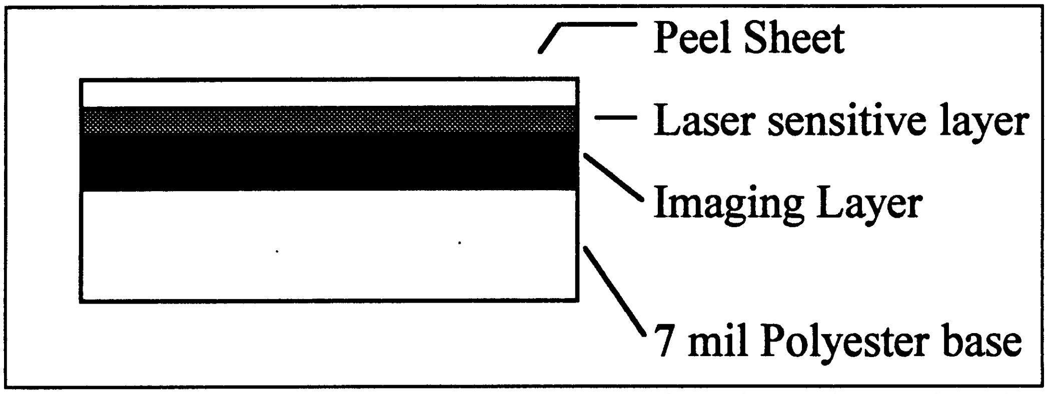


Figure 2.1: Simplified Cross-Section for Helios Dry Film (adapted from Polaroid Marketing Publication)

An image is produced when laser energy from a high-powered gallium arsenide solid state laser diode is focused onto the film.[6] Absorbed heat energy causes a phase transformation at the interface between the thermally active layer (B) and the Carbon layer (CB) leading to a strong adhesion between the two layers only at the site where the laser beam energy is absorbed. The energy required to bring about the transformation must be deposited at the interface in a short period of time, typically on the order of a few hundred nanoseconds. After the adhesion spots are formed, the film is "developed" by mechanically separating the sandwich, leaving the written image on one substrate and its

---

[6] Description of imaging process adapted from external Polaroid Marketing Publication known as "White Papers", 1993

negative on the other. The written image is covered with a layer of thermal transfer material to seal the image and protect it from scratches *(Refer to Figure 2.2).*

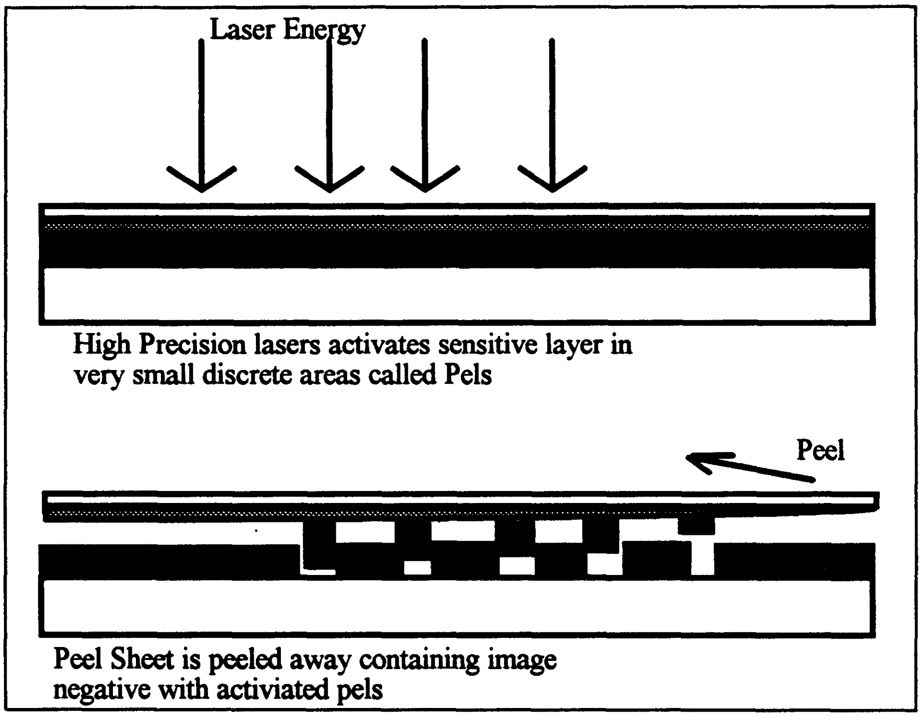


Figure 2.2: Creation of a Helios Dry Image adapted from Polaroid Publication

The quality of the final image depends not only one the quality of the carbon-based media, but the ability of the media to perform well in this highly interactive system. There are a number of major sources of interaction between the hardware/software and the media in the imaging process as exhibited in Figure 2.3. below.

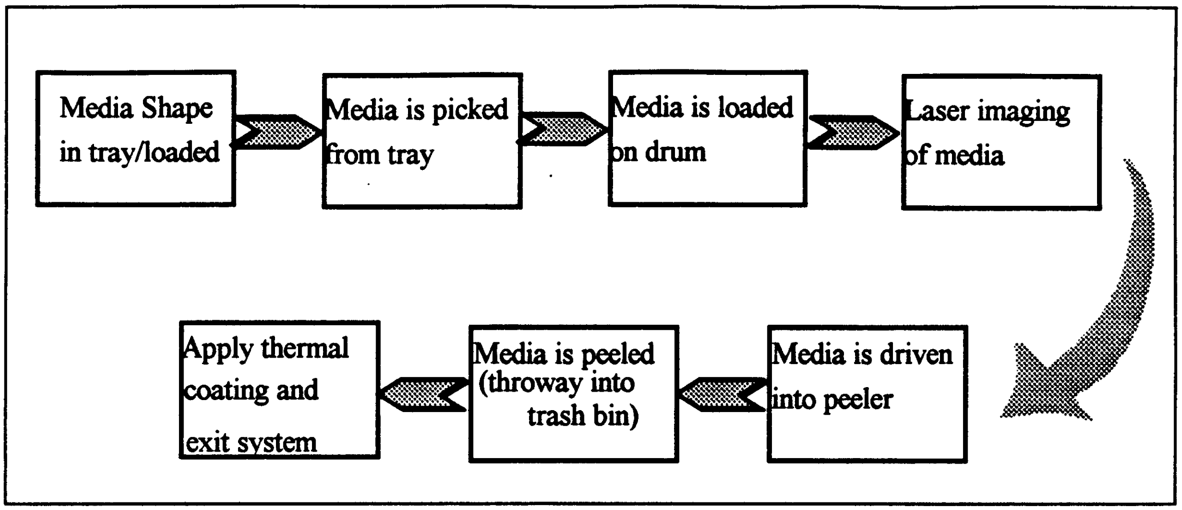


Figure 2.3: Major Sources of Hardware/Media Interaction

During image processing, the film media must have the correct physical attributes such as size, shape, curl, etc., to perform well mechanically in the machine as well as have good imaging properties.

2.2. Learning from Customer Feedback

A number of specifications for the finished media was set early in the program and documented in the Helios 810 Laser Imagery Specifications. As the number of internal, beta site, and early sale customers using the system continues to grow, the organization discovered that other factors not originally anticipated might be affecting the system's performance. The Helios team received customer feedback through a number of channels:

- Internal Polaroid customers;
- Beta site or early use customers;
- Sales reference accounts; and
- Trade Shows and Demonstrations.

The performance information the team received from these sources was being used on a limited basis to determine which of the elements of the system affected system performance. We believed there were additional opportunities to improve and accelerate this learning if a focused team from hardware/software and media manufacturing and engineering could perform root-cause analysis of the failure or interaction. There would also be value in creating a controlled environment were hardware and media manufacturing and engineering could study how different combinations of media and hardware affected systems performance. This system testing could be incorporated into the manufacturing release process and help accelerate learning.

2.3. Speeding up the Product Delivery Process

It was the aim of Polaroid management to use Norwood (N2) as a learning environment for media manufacturing. The site was built in the 1970's as the coating facility for the Polavision product; an instant 8 mm movie film. At that time, it was one of the most sophisticated coating facility within Polaroid or among its competitors. However, there was little demand for the product and the Polavision project was canceled. During the 1980's, the plant was used to coat a related set of products that shared elements of the Polavision technology such as an instant 35 mm slide film.

As the Helios opportunity emerged, Polaroid management saw an opportunity to use the N2 facility to improve the product delivery process. The N2 site would take on more missions in addition to its "Pola" related products. It could serve as the low-volume manufacturing site for 810 media; the process and product development site for other Helios products; and provide the technology support for the start-up and scale-up of a new high-volume coating facility in southern Massachusetts (MA).

If the goal is to use N2 to learn how to get Helios products to market faster, then Polaroid required a greater amount of management by fact than the Helios team could perform in the current environment. Like most manufacturing activities, media manufacturing is highly data driven. However, there were few tools or methodologies in place at N2 to use these volumes of operating data.

Each owner of a major process or test area related to Helios collected the operating data they thought was important for controlling the process or measuring the quality of the product. This information was stored in a number of disparate sources such as paper, PC based spreadsheets, MAC based spreadsheets, on the VAX mainframe, or in process control computers. The hardware manufacturing site was also generating information that could be useful in determining how current combinations of imagers and media interacted. However, there was no standard method to gather, organize, and analyze this valuable operating data to make decisions.

2.4. Long Lag Times in the System

In order to ensure the quality of the media at the time it is manufactured, the media organization needs to be able to quantify which factors in the manufacturing processes that affect the overall performance of the media in the Helios system. This task proves to be quite challenging because of the lag time in the production and distribution system between the initial selection of raw materials and release of finished material that was formatted and packaged for customer use.

2.4.1. Media Coating as a Continuous Process

The Helios media is produced using proprietary continuous coating and drying processes. The end result is a media laminate which is formatted into finished sheets 8x10 inches in size.

The fluids used in coating process are prepared in the chemical mix area in a number of batch mix processes. The fluids are then filtered and pumped to dispensing tanks. Most of the fluids are prepared within twenty four hours of the run but some can be prepared many days in advance of the run. Many of the dispensing tanks are of sufficient size to hold enough fluid to coat media for an entire production campaign. There are a number of smaller dispensing tanks that can be used to facilitate testing of new batches of raw materials or fluids.

There are opportunities to collect process information either in-situ or through a series of off-line evaluation steps. The properties of each fluid, such as pH, viscosity, percent solids, etc. are measured off-line in the analytical laboratory. These measurements are performed before the start of the production run and each morning as the run is in progress. The flow rate of each fluid is recorded at the start of the run and at regular intervals throughout the day. Some of the ovens are profiled at the start of the production run. There are temperature and air flow meters monitoring the temperature and flow rates of air entering and leaving each oven.

There are a number of parameters that the line operators can measure, chart, and control while the roll is in process. For example, the optical density of the carbon black is measured either off-line or in-situ and compared to a set-point. If the density is low the supervisor can either adjust the coating flow or call for a new mix of the carbon black fluid. The line operators also actively look for surface defects and pinholes and attempt to eliminate the sources of these defects if possible. Additionally, if the measurements are made in off-line in a laboratory, any feedback and corrective action is usually applied to the next roll rather than the roll the measurements are taken from (due to the time delay introduced by taking a sample from the head or tail of a roll, transporting the sample to the lab, and the time necessary to make the measurements).

While the line supervisor and operators have some limited control over the physical attributes of the product, there are less measurements that can be taken in-situ to predict the final imaging performance of the product. The most important sources of lag time or informational delay in the media manufacturing system is due to the fact that the coated film has to be fully processed, and formatted before it is ready for use in an Helios printer. If the media requires any additional time to "age-in" before it is fully functional in all types of environmental conditions a customer might experience, this extends the lag time significantly. While a notable amount of performance testing or evaluation can be performed during production or while the media was "fresh", this data is used only to predict or forecast the final performance of the aged-in media.

There is a systematic effect to these long lag times or delays. Some of these delays can be eliminated by instituting more in-situ process testing. However, until we have the ability to accurately predict the final outcome of the media at the time of coating, the total cycle time will remain long. The longer the delays, the more difficult planning and inventory management becomes. Uncertainty about the outcome of any given run causes management to increase the number of production runs and the amount of raw materials on hand at any time.

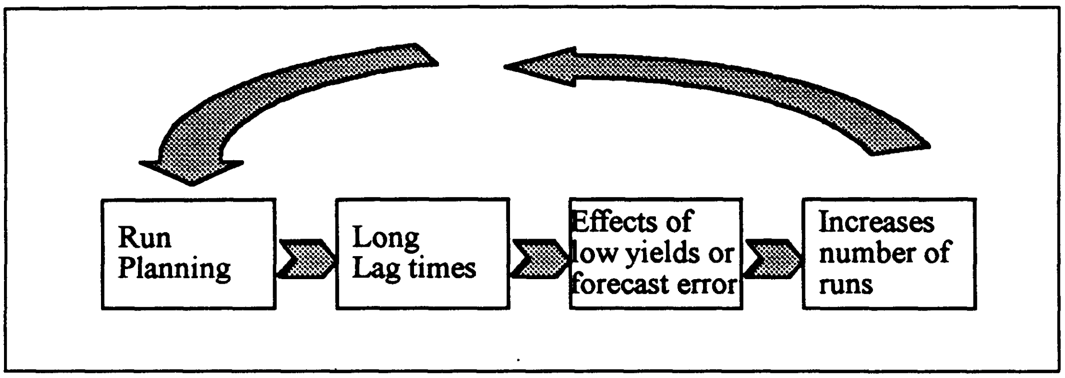


Figure 2.4: Impact of Long Lag Times on Manufacturing System

Ultimately, the company would like to move to a production environment where the media is coated , formatted and shipped on the day of coating.

2.4.2. No Opportunity for Rework

In a large number of continuous flow manufacturing systems, such as paper production, food processing, steel manufacturing, there are opportunities to correct manufacturing errors. This errors can be detected in subsequent quality inspections or through in-situ process monitoring. While this corrective action is time consuming and expensive, it is viewed as a viable option when there are large variations in raw material feed stocks and processing conditions. The most appealing outcome in these situation is to reduce process variability and increase the manufacturing robustness rather than inspecting quality into the system.

In the Helios film world, there is no opportunity to rework the product. Once the film media laminate has been created, it will either prove to be conforming product or non conforming product. Most of the non-conforming product is either scrapped or used for internal only applications were suitable. Since it is difficult if not impossible to adjust the imaging or physical attributes of the media once processing is complete, Polaroid must adopt a mind-set of getting it right the first time. This requires that the development and manufacturing team work to understand and reduce sources of variability in the raw materials, fluid processes, and coating processes. It is highly desirable to manufacture a product that is robust to minor changes in raw materials and coating process condition.

2.5. Increasing Pressure from Outside Forces

There was increasing pressure on the Norwood and High Resolution organizations to learn faster. While the quality of the media released to the customer was very good, it represented a final yield that was well below established targets. Polaroid senior management was anxious to see the media yields increased by the end of the year. The hardware group had also identified a significant number of media/hardware interactions that affected overall system quality and had to be corrected.

Additionally, there was a pressing requirement to put into place a Manufacturing release system which would satisfy the FDA that Norwood was using good manufacturing practices for methods used in manufacturing and packaging the media. The FDA reserves the right to audit the manufacturing sites of any company producing medical devices. As the Helios product was now generally available to customers, they could be put on notice and at any time receive an FDA audit team. In addition, the media organization had also committed to be ready to seek ISO 9001 certification in 1994. The requirements and activities to satisfy the ISO 9000 certification are similar to that of FDA GMP. The FDA defines a manufacturing release as a program that consists of procedures adequate to assure that the following functions are performed[7];

---

[7] "Good Manufacturing Practics", Code of Federal Regulations, Food and Drug Adminstration, CFR 21 - Part 820

1. Review of production records;
2. Approval or rejection of all manufacturing materials, components, in-process materials, packaging materials, labeling, and finished medical media;
3. Identifying, recommending, or providing solutions for manufacturing release problems and verifying the implementation of such solutions; and
4. Assuring that all manufacturing release checks are appropriate and adequate for their purpose and are performed correctly.

These functions were difficult to perform in the current manufacturing environment. While the existing manufacturing release system had some of the elements listed about, the bulk of the "quality" effort was spent testing and evaluating the finished media against the image performance specification and releasing the media when it meet that specification. Since it would take weeks or months before the formatted and packaged media met the performance specification, there was little opportunity to use that information to improve the product or increase the manufacturing yield.

A manufacturing release process that conformed to the FDA GMP requirements would provide a management framework to use operating information to continuously improve the product and processes.

3. Building the Learning Foundation

In order to respond effectively to the concerns of Polaroid management, the hardware group, and other outside forces, N2 required effective management of the volumes of operating data. The organization had responded with an initiative to design and build an Integrated Information System (IIS). In mid-1993, the effort was in the "defining requirements" stage and a completed system was probably over a year away. In addition, without an understanding of what variables or interactions of variables might effect the performance of the media in the Helios System, it was difficult to specify all the requirements of the IIS.

3.1. Lack of a First Principle Model of System Performance

The development of a mathematical model that accurately specifies systems performance is feasible for many applications in the chemical process industry. These models are designed on a first principle's basis or through the development of a simple empirical model. Examples of these systems are found in the petroleum refining industry and batch chemical manufacturing. In these instances, process engineers have applied model-based techniques to optimize system performance and control the manufacturing processes.

For the Helios media, the formulation of a first principles or simple empirical model of system performance was quite difficult. The film media product had been empirically designed by a number of chemists and engineers and they lack a quantitative understanding of the systemic chemical/mechanical/electrical properties. The manufacturing technologies used in coating and finishing Helios media might be quite familiar to the group, however coating processes are notoriously difficult to model mathematically. However, without a "first-principles" or easy to use empirical model of system performance, the opportunities to use traditional process control methods to specify the outcome and reduce variability are lost.

Because the Helios media team lacked a first principles understanding of systems performance, technical decision making was quite challenging.

- There was lag-time built into the system. By the time the team learned there was a potential performance problem with the Helios media, one to many time periods had passed since the time the media was coated and formatted.

- The performance of the media was evaluated in three different sets of environmental conditions. These conditions were meant to reflect the range of possible operating conditions the Helios System and media might be exposed to in the customers environment:

    - Room temperature
    - Hot and Dry (Hot/Dry)
    - Hot and Wet (Hot/Wet)

- The performance of the media across these three sets of environmental conditions might not be uniform. That is, the performance of the media in a Hot and Wet environment might be satisfactory while the performance in Hot and Dry might not.

- The time it took for the media to perform satisfactorily or "age-in" in all three sets of environmental conditions varied.

- The performance of the media in the various environmental conditions might be highly interdependent. What makes the media a good performer in a Hot and Wet environment might make it a bad performer in a Hot and Dry environment.

- There were a large number of potential sources of variability in the manufacturing processes *(refer to Figure 3.1)*:

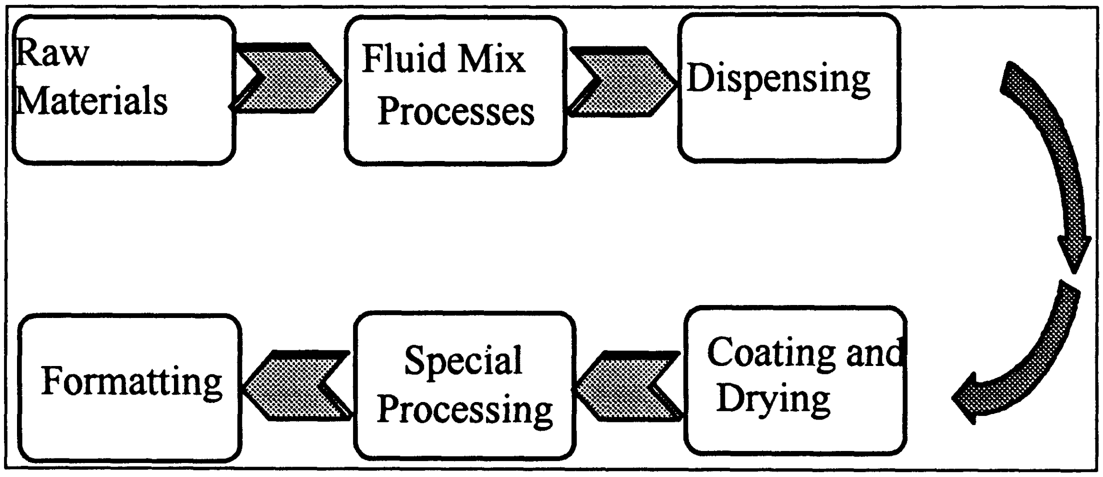


Figure 3.1: Sources of Variability in Manufacturing Processes

- While a significant amount of information was collected about the raw materials, fluids, coating and drying and other processes -- this data was not available in a form that could be used for analysis or decision making.

Because of these challenges, the media team was use to making quite a lot of assumptions about what factors or key process parameters might affect system performance and how these factors inter-relate. They were, in affect, attempting to perform an multiple objective optimization on a complex system with a very limited amount of facts. As a result, most attempts to steer the processes toward a given system performance outcome were not usually successful or repeatable.

3.1.1. Cost of Full Scale Experimentation is Great

The cost running experiments on the full scale production coater is very high. Like most high volume continuous processes, the N2 line was designed to run optimally when the process conditions are held constant. Most experiments involve either changes in the dispensing fluids or changes to the coating flows and or oven temperatures. Any of these changes are disruptive to the flow of product and can introduce errors.

There are actual hard dollar costs associated with running experiments. First, running a simple orthogonal array (L4 or L8) experiment can reduce the output as much as 50% on any given production day. Second, we have to factor in the cost of additional analytical, in-process and quality testing of each cell of the experiment. Finally, there is the cost of additional raw materials, fluid mixes, and labor associated with running the experiment.

Many of the experiments run on the production coater to this point were one-at-a-time type of experiments. While this method would occasionally highlight a factor which effects product performance, it was hit or miss. The group would also commit what I would call a grave offense. They performed many one-at-a-time factor experiments, or simple orthogonal arrays and then did not extensively analyzed the data.

Because of theses cost factors, we have to view test time on the production line as a scarce and valuable resource. Therefore, we must learn as much as possible from past production runs, experiments, and analytical findings before we plan subsequent test runs. The team should run designed experiments to achieve the following (Schmidt, 1991):

- improved performance characteristics
- reduced costs; and
- shortened product development and production time.

This means that before we even start to plan our experiments, the team has to have a good understanding of the problems and know what response or output variables we need to measure. These characteristics should be related to the customers needs and expectations. To accomplish this, we must incorporate a data driven approach to process learning into our day to day activities of assuring the quality of the product.

3.2. Developing a Data Driven Approach to Process Learning

There has been some work done by researchers (Saraiva, 1992 and 1993) to develop decision support or learning methodologies for manufacturing environments lacking first-principles or simple empirical models. The goal has been to apply a systematic effort to the exploration and analysis of existing operating data records, leading to continuous improvement of the product and manufacturing processes. Because of the complexity of the Helios system -- the high degree of interaction between the Helios media and hardware; a number of complimentary data analysis techniques and tools were evaluated and used to improve process understanding.

What makes the Helios system so stimulating is that the possible data set is large and involves a mixture of data types, and non-standard data structures. That is, the quality measurements are subjective and non-parametric and can change with time, temperature, humidity, and evaluation techniques. The manufacturing process data is usually continuous and normally distributed, while information regarding raw materials can be discrete, continuous, or categorical data. Additionally, since this "operating data" was not readily available, the we had to be flexible in our choice of data collection methods and tools.

The process of developing a methodology was itself guided by the PDCA process improvement cycle -- Plan, Do, Check, Act.

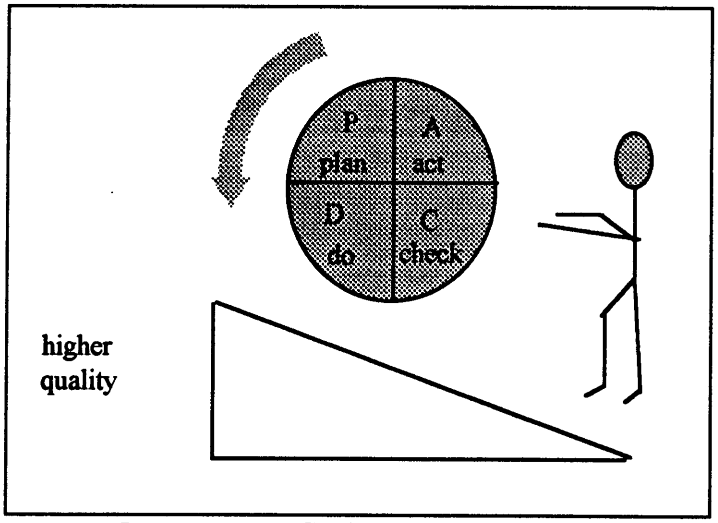


Figure 3.2: Continuous Improvement Cycle (PDCA) adapted from Shoji Shiba

PDCA symbolizes the principle of iteration in problem solving -- gaining understanding and making improvements in a step-by-step fashion. Teamwork and communication were key ingredients for success. The PDCA cycle was useful in identifying what:

- Data is needed for the manufacturing process analysis;
- Best methods to collect the necessary data;
- Tools and techniques are applicable for process analysis;
- Systems tests are required to identify interactions and reduce variability in overall system performance; and
- Learning and methodologies that should be incorporated into the manufacturing release system and the new management information system.

3.2.1. Description of Data Analysis Tools Available

The statistical tools and methodologies used in this process include:

- *Data Acquisition Methods*

  A data driven methodology to process analysis is dependent on exploring and analyzing accurate data to solve problems. Manufacturing data comes in many forms including quantitative process information and qualitative quality information. To collect process and quality data, we employed operator run sheets, batch sheets, spreadsheets, and automated data collection systems.

- *Exploratory Data Analysis*

  Exploratory data analysis is the first step in identifying and understanding sources of variability in the manufacturing processes. Graphical based techniques allow us to summarize and display the data we measure and collect from the manufacturing processes and quality testing. These tools include simple histograms and other useful data displays such as Stem and Leaf displays, Box-and-Whisker plots, Digidot Plots, and Probability Plots. Statistical analysis systems such as SAS© or SYSTAT© contain very complete Exploratory data analysis packages.

- *Statistical analysis using univariate techniques*

  Univariate diagnostic techniques are useful in identifying cycles and trends in process or quality data. The aim is to show the nature and the strength of relationships between two variables. Scatter plots, Correlation, and Least squares analysis can be used to tell us what these relationships are like and if possible, attach a numeric value the assess the associations in terms of a single number.

- *Statistical analysis using multivariate techniques*

  In this system, we have to deal with a large number of physical variables in our data set. There are a number of multivariate techniques like Principal Components Analysis which reduces a data set into a small number of latent variables. The multivariate statistics can then be used to build models that relate quality variables to process variables.

- *Classification Decision Tree Analysis (CDT), also known as CART*

  Classification decision tree, also known as binary decision trees, is a sequential method to predict the quality value (or corresponding conditional probabilities) that is associated with a particular set of measured variables. CDT's can be used to process quantitative, qualitative, and categorical information. A hierarchical tree or branching pattern can be induced to identify the critical limits of key process parameters for acceptable operation.

- *Design of Experiments (DOE)*

  The Design of Experiments is a systematic approach to comparative studies that allows us to perform experiments that ensure the validity of experimental results and that lead, in relatively few experimental runs to precise estimates of the effects these factors have on the response. It can be especially useful in identifying the interactions among key operating variables during process development.

3.2.2. Need for Problem Identification Techniques and Tools

There was also a need for the application of some Total Quality Ownership tools and methods to assist in problem identification and structured problem solving. These tools and methods included process mapping, Pareto charts, fish boning, and the Kepner®

Tregoe problem analysis techniques. We found that identifying the problem is the most important step in reactive process improvement.

The Kepner® Tregoe Problem analysis technique is published and taught by Kepner-Tregoe, Inc. of Princeton, NJ and has been used within Polaroid to aid with problem analysis. The Kepner® Tregoe technique of problem analysis is "a process for creating visibility within the cause-and-effect relationships. It starts with a careful delineation of what can be seen -- the effect to be explained. It moves from that specific effect to the limited, special cause which produced that effect". This method is based on eight steps:

1. Identifying the Deviation
2. Specifying the Deviation
3. Defining the Boundaries
4. Examine the Distinctions
5. Look for Changes
6. Statement of Cause
7. Testing For Cause
8. Verifying the Cause

For more complete details on this methodology, refer to Kepner® Tregoe for course materials or Kepner® Tregoe Executive Problem Analysis and Decision Making book (1973).

3.3. Getting Started by Exploring System Performance Data

The N2 organization had completed a number of mid to high volume manufacturing runs (relative to the given capacity of the N2 coating line) of the Helios media since November of 1992. There was a sizable amount quality test and evaluation data available from these runs. The system performance data was of three types:

- Image quality measurements
- Mechanical property measurements
- Helios system reliability testing

Image quality was evaluated by observing or measuring a number (5 to 10) of characteristics of a printed image in each of three or more sets of environmental conditions. The total number of quality measurements (Q_1, Q_2,...Q_n) was large (15 to 30).

Printed images are generated using hand-cut samples or formatted samples of media in an early generation Helios Imaging system. The objective of the image testing is to determine if there is accurate reproduction of an target image which is made up of large number of gray-scale pixels. Most of the quality checks are made with the un-aided eye or with a low power (10x) loupe. There is an attempt to identify the defects separately; such as ragged or misshapen pixels or pixel units, black spots, hazy or milky appearance, poor reproduction of the desired density levels throughout the gray tone scale, and others. The presence of any or all of these defects might result in an image which is unacceptable for diagnostic use.

The mechanical properties or peel strengths of the media are also measured in each of the three sets of environments using a special image pattern. The resulting quality of any image depends on the way the layers within the media fail adhesively or cohesively upon the separation of the polymeric sheets within the imaging system. The objective is to perform peel strength testing at the same time image quality is measured.

The image and peel testing was performed on a given production run at specified time intervals. For example, image and peel testing could be performed when the media was *T* periods old, 2*T* periods old, etc. for a specified time period. A production run is defined as a day or series of contiguous days when media is coated on the N2 production line. On a given production day, the coating line ran from as little as 10 hours to as much as a twenty four hour continuous basis. During a given production day, a large number of individual rolls of laminar media can be produced.

3.3.1. Organizing the System Performance Data

The N2 team had begun to categorize or group image defects within a production run. However, it was quite difficult to use the System Performance data in its current form to categorize image defects across a large number of production runs. To make the analysis easier, the Performance data for a moderate number of production runs was combined in a single database using a PC based relational database product by Microsoft called Access ©. We chose Access because it allowed users to import data or tables from Borland's Paradox, Lotus 123, or Microsoft Excel and other products and also had an easy to use Query language based on Standard Query Language (SQL).

The first step to exploring System Performance was to categorize or group defects for all the production runs to determine if there was some patterns in the data. Before the data was plotted, it was organized into a number of <u>cases</u>. A case represented a roll or set of rolls of media from a given processing day which were treated identically. That is, they used the same set of raw materials, fluids, and process conditions. Each case on a given processing day could be described as either standard or test:

- Standard - run using a standard set of process conditions and formulation or composition of matter; and

- Test - run using non standard process conditions, raw materials, fluid processes, or formulation or composition of matter.

The "standard" structure for the Helios product was modified slightly during this time frame. Therefore, the "standard" from run one was not necessarily the same as the "standard" from run six. The number of cases on a given processing day ranged from 1 to 10 or more.

The System Performance data was used to determine which class a given case was in. We defined a class as the final quality outcome of the product in a given environment. There could be *C* number of classes, that is $C = (1, 2, \ldots J)$. Our first attempt to categorize what case a class was performed using the image evaluation data. This data was generated by the Technical Evaluation group by testing the media in the three environments at set time intervals.

Time	Room Temp	Hot and Dry	Hot and Wet
T	$Q_{1rt}, Q_{2rt}, \ldots$	$Q_{1hd}, Q_{2hd}, \ldots$	$Q_{1hw}, Q_{2hw}, \ldots$
2T	$Q_{1rt}, Q_{2rt}, \ldots$	$Q_{1hd}, Q_{2hd}, \ldots$	$Q_{1hw}, Q_{2hw}, \ldots$
4T	$Q_{1rt}, Q_{2rt}, \ldots$	$Q_{1hd}, Q_{2hd}, \ldots$	$Q_{1hw}, Q_{2hw}, \ldots$
NT	$Q_{1rt}, Q_{2rt}, \ldots$	$Q_{1hd}, Q_{2hd}, \ldots$	$Q_{1hw}, Q_{2hw}, \ldots$

Table 3.1: Performance Quality Measurements

The majority of the data in this quality data set (Q) is discrete data rather than continuous. Most quality measurements are rated on a subjective basis on a scale of 1 to 10 (in units of one). In addition, this measurement was not a traditional control variable in a Process Control System, instead it is attribute data. That is, it represented an image characteristic of the product in a given environment and at a given point in time.

3.3.2. Using Graphical Analysis to Classify the Quality outcome

For a single quality measure or attribute of the system (i.e. Q_{3rt}) it was now possible to track the performance of a given case as a function of time (T). We could compare these "aging curves" or time-series profiles from run to run. A set of sample aging curves are shown in the Figure 3.3. below. For this quality measure, Q_{3rt} and Q_{3hw} the media is considered "aged-in" when the value of the attribute is greater than or equal to 9 out of 10.

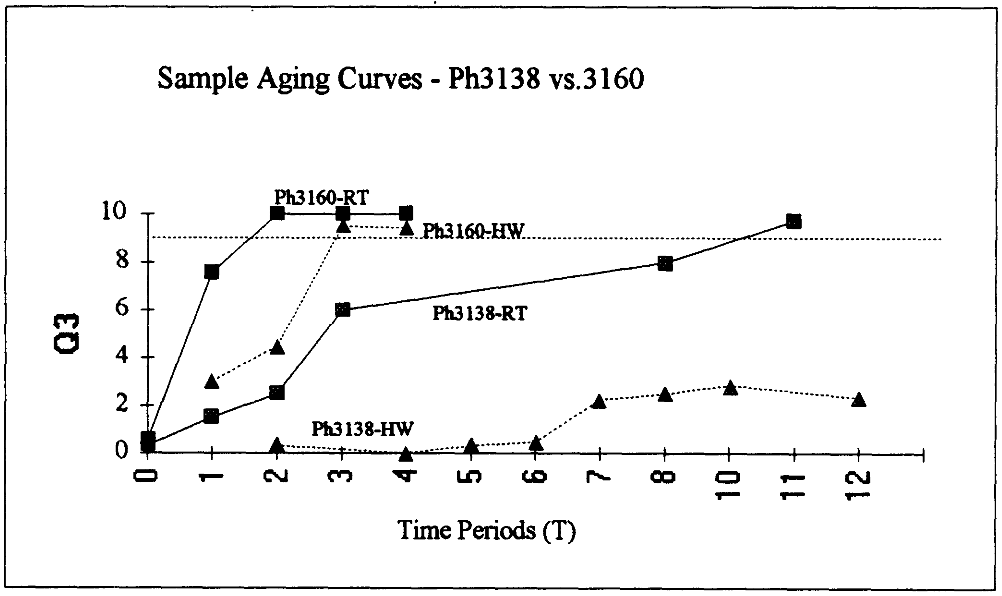


Figure 3.3: Sample Aging Curves for Media in Two Test Environments

For a number of the characteristics, the quality attribute did not change with time. There was also a group of measures were the image quality of the media changed as a function of time. For a given quality attribute in a specific time period, it was also possible to plot the distribution of this discrete data using histograms. At the $2T$ time period, the image performance ranged in value between 0 and 10. By the time the media is re-tested at time $10T$ or greater, the product was usually fully aged-in and the Q_{2hw} consistently takes on values of 8 or higher (unless a failure occurs). Realistically, once the product has sufficient time to age, it is either good (or better), or bad and has a binomial type of probability distribution.

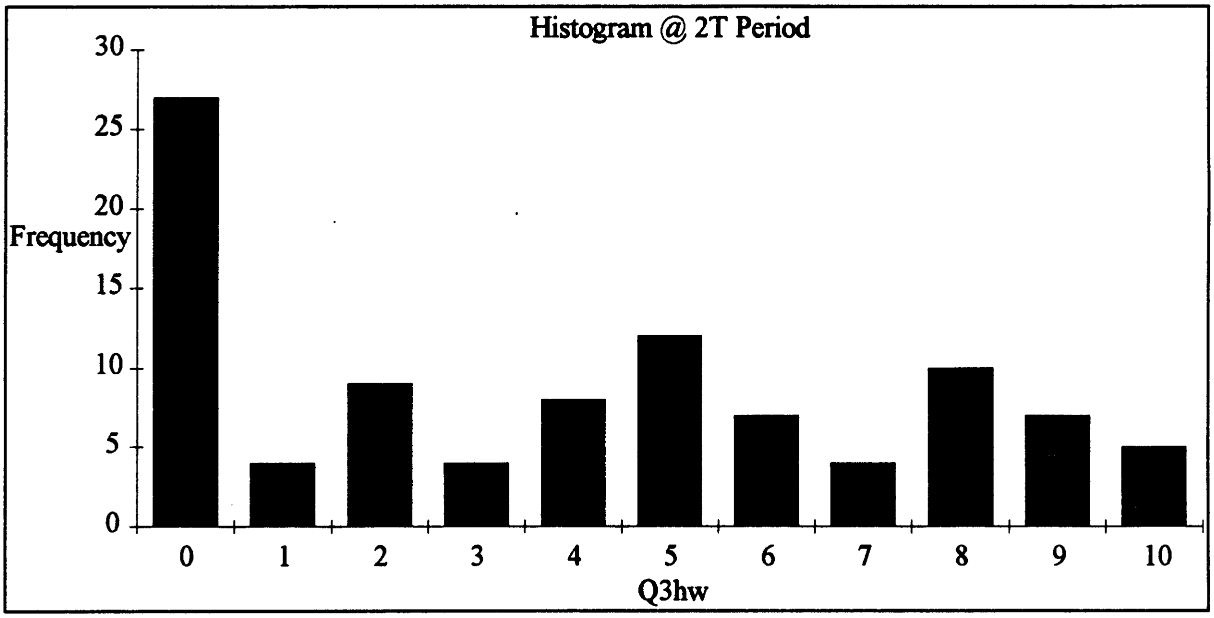


Figure 3.4 Histogram of Quality Indicator at 2T Period

The standard and test materials seemed to fall into three distinct classes for a given quality parameter:

- Quality was uniform and aged consistently across all three environments
- Quality was non-uniform and aged inconsistently in at least on of the three environments
- Quality was non-uniform and aged inconsistently in at two or more environments

Media could be classified as either an good performer, a Hot and Wet performer, or a Hot and Dry performer or a Combination performer. Typically, media in the Hot/Wet performer category eventually "aged-in" and had consistent performance across all three environments. Media that exhibited poor performance in the Hot/Dry environment continued to degrade with time and was unacceptable for use in the customer environment. This assumption was verified through a series of printer performance tests at the Hardware manufacturing site. Media in that category was either scrapped or saved for use in selected internal Polaroid activities.

Using the test information from the database, it was also possible to relate a quality performance measure to the peel measures for a given production day and roll. While there were less information available to perform this comparison , there was a correlation between image performance and peel strength of the same age and environmental conditions.

From these classification procedures, the team formed a number of hypotheses, based on a rudimentary understanding of the physical and chemical properties of the system, to explain the resulting quality of the media. Media exhibiting Hot and Dry performance could be the result of a structure that was too strong. However, there were a large number of process or raw material variations that could produce this resulting system (for example $Q_1=f(x_1,x_2,..x_n)$).

At this juncture there were two basic approaches to validating a given hypothesis. One was use our rudimentary understanding of the media structure and imaging system to select factors for designed experiments. The second was to learn from the historical data (*N* number of cases) which set of process variables were the key determiners of system performance. The cost of running experiments was quite high, so there was strong motivation to gather, organize, and explore the historic operating data before committing further resources.

3.4. Exploring the Historic Operating Data

The complexity of the Helios System is great. It is not enough to improve the quality of the media in a single environment. There is strong motivation to optimize performance in all three environments simultaneously. If that was not possible, it would be beneficial to minimize the possibility of producing media that performed unsatisfactorily in a Hot and Dry (Hot/Dry) environment. If the group had to make a trade-off, it was to make media that did not have hot/dry performance related issues and live with any short term variability in room temperature or hot and wet (Hot/Wet) performance.

The basic purpose of the classification study was to uncover the predictive structure of the Helios system. The aim was to gain an understanding of what characterizations or conditions of the raw materials, fluid processes, coating and drying processes or interactions of these variables drive Systems Performance in the three sets of environmental conditions. Once we gained this understanding, we could develop a set of manufacturing rules or guidelines which if followed will result in product which satisfies the customer's requirements.

3.4.1. Defining the Decision Space

The set of possible operating variables contained in the *decision space* (Saraiva), also known as the *measurement space* (Breiman, et. al.*)* for this system is large. The measurement vector $\mathbf{x} = (x_1, x_2, x_3, \ldots)$ for a given case is defined as containing all possible decision variables or measurements made on that case. The set of measurements are arranged consistently in the same order. For example, x_1 is the pH of fluid A, x_2 is the percent solids of fluid A, etc. The measurement space X is defined as containing all possible measurement vectors. The members of the measurement space represent the key process variables (independent, controlled parameters) as well as uncontrolled parameters. For the Helios Media, the team could make a number of measurements on:

- *Raw materials*
    - From 20 to 50 individual raw materials.
    - Measurements include pH, viscosity, % solids, etc.

- *Fluid mix processes*
    - From 5 to 10 fluids or sub-mixes required for coating.
    - Fluid mixing comprised a series of batch operations.
    - Measurements on the fluids include pH, viscosity, % solids, mix times, etc.

- *Coating and Drying Processes*
    - Dispensing, coating, drying of 5 to 10 fluids.
    - Coating is done in successive steps.
    - Measurements made at each coating station include flow rates, pressure, temperature, etc.

The number of variables in the measurement space could be as high as 100 or more. The most desirable situation was to build the measurement set for each case without making a decision, a priori, if that variable was important to the predictive structure. However, as noted, the measurement data was contained in a large number of disparate sources such as paper records and notebooks, PC spreadsheets, and mainframe spreadsheets. While this approach was feasible, it would be quite time consuming to construct a database or repository containing X. A second approach was to screen the variables using either univariate or multivariate criteria, process knowledge, or the results of prior studies or experiments, and organized so that the information for each case could be easily queried and grouped. The team would also analyze each unit operation or processing step to attempt to cull through the 100 or more variables to develop a smaller working measurement set.

3.4.2. Univariate Analysis

Univariate diagnostics are especially useful in chemical batch manufacturing by reducing the data represented by a time series profile into a few key variables. For example, consider a first-order exothermic chemical reaction. A time versus temperature plot is a useful diagnostic tool. From that plot, one can calculate both the slope of the curve and the area under the curve (corresponding to the rate of reaction, etc.). This procedure can be repeated for both "*good*" and "*bad*" batches. The resulting calculated univariate diagnostics can become the basis of control chart information.

This approach is quite valid if the resulting good and bad performance can be isolated or attributed to a single processing unit. The team successfully applied univariate analysis to steps of the finishing processes when the media is formatted for use in the Helios system. After the set of critical diagnostics were identified, the technicians in the finishing area are given the responsibility to create and review control charts as a routine production activity.

We also applied univariate analysis to a number of the batch fluid operations. Currently, the fluids are evaluated each morning of the production run for gross fluid properties such as pH, percent (%) solids, viscosity, and others. The chemical mix operations group has set specification limits for each fluid based on historic performance and past experience with the product. For example, the original targets were established based on the capabilities of the coating processes and the product requirements. The analytical lab measures each batch and the chemical mix group established current property targets using statistical process control techniques. We can track each fluid and measure its variability about the mean, but it has been a complex process to link the performance of the final product with gross characteristics of each fluid.

While it was difficult to isolate the effect of a single fluid on the final product performance, there are a number of key process characteristics that can be used to identify good or bad fluid batches. For example, there were a number of instances when manufacturing experienced unusual difficulties attempting to coat the CB layer. An analysis of good versus fair versus bad runs pointed to a difference in the fluid mix process.

The CB layer is created by mixing a special paste containing carbon black with a (aqueous based, organic) binder Z. We charted the viscosity of the mixture containing Z as function of time from the point that mixing was complete until the batch has stabilized. This resulting mixture is major component in both the carbon layer as well as another layer of the system. From the slope of the curve (*see Figure 3.5. below*), it was determined the Z mixture needed to stored in the vessel for at least 12 hours at room temperature conditions after mixing to stabilize.

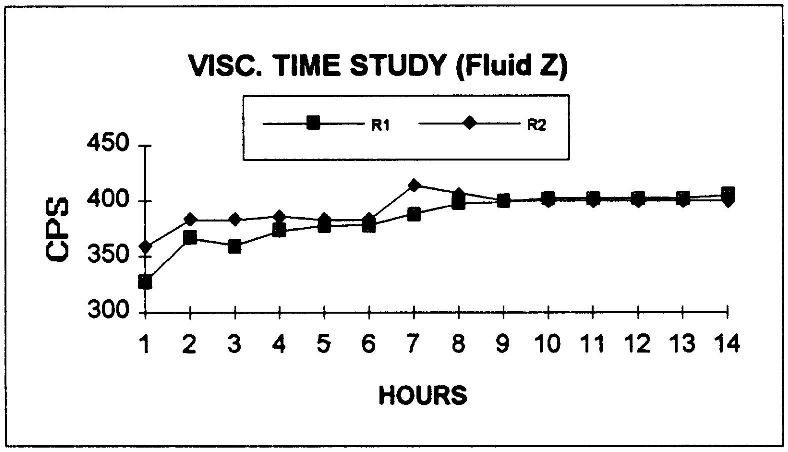


Figure 3.5: Viscosity of Fluid Z versus Time (Repeated in two Campaigns)

When the sub-mixture containing Z was used in subsequent processes before the viscosity had stabilized (Fluid Z contains a long chain polymer which uncoils and swells in solution), the resulting final fluid mixtures still appeared to be within normal (2σ) specifications for pH, viscosity, and percent solids. However, there was a consistent marked decrease in the coat-ability of the carbon fluid, and a corresponding increase in the need to replace dispensing filters. While this deviation might not translate to a change in the imaging performance of the final Helios product, the coating problems resulted in a decrease of the final product yields and more production line down-time.

3.4.3. Multivariate Analysis

The univariate analysis of a unit operation or set of processing steps may uncover a number of key process variables that are highly correlated or coupled. Unless one can make strong assumptions about the independence of these process variables, the number of parameters needed to specify the system completely increases. This increases the complexity and dimensionally of the data set or measurement space. Most of the multivariate techniques available allow the use to compress or reduce the dimensionally -- the total set of univariate parameters into a fewer number of derived or latent variables.

Like univariate techniques, multivariate analysis works well when good and bad product performance can be the attributed to the function of a single processing unit or step. For example, multi-parametric analysis has been successfully applied to chemical batch reactions or Reactive Ion Etch (RIE) reactions in semiconductor processing.[8] While a RIE process was difficult to model on a first principles basis, a satisfactory empirical model of the appropriate functional form could be created and used to control the manufacturing process.

---

[8] Based on reserach by this author, Andra S. Weissberg, while at IBM Corporation, Semiconductor Operations. Results presented at an internal IBM Technical Conference in Septermber of 1986.

The use of multivariate methods to build a predicative process model of the Helios manufacturing system was quite complex. It requires the iterative analysis of each unit operations or processing step to identify the critical process parameters. Ideally, it was desirable to be able to build a first principles or simple empirical model of each separate unit operation and be able to aggregate these models. However, that required, a priori, knowledge about all the processes the team did not possess. Each of these individual unit operations or processing steps comprised subsystems that were highly coupled and interactive. Additionally, any single quality measurement, such as Q_{1rt}, could not provide a complete and meaningful description of the performance of the product.

I attempted to perform multivariate analysis for the coating processes using a set of univariate process parameters. This resulted in a functional model explaining less than 50% of the total variation in the system. In addition, the model was not of a form that was easy to use to control the manufacturing processes. I was also concerned that there was a lot of noise in the measurement data that made multivariate reduction tools challenging to work with. Even the quality outcome data was difficult to work with. Each quality measurement was highly subjective and there was a fine-line between good and bad performance.

3.4.4. Classification Decision Trees

3.4.4.1. Motivations for a "Non-traditional" Learning Methodology

The rationale behind classification decision trees is that it may not be necessary nor desirable to build complicated mathematical models to deal with complex situations. Classification Decision Trees (CDT) can help to find a point of view that makes intricate situations seem reasonable. The learning methodology I employed was described by Saraiva and Stephanopoulos (1992) in a number of published papers. Saraiva formalized a Data-Driven learning framework to analyze and continuously improve complex manufacturing systems for which neither first-principle models with acceptable accuracy are available, nor empirical models with appropriate functional forms are known. He advocated employing CDT's when there is a considerable amount of operating data available on a routine basis. Even when there was only moderate amount of data available (always less than 1000 records), it is possible to find solutions that results in a significant performance improvement over the existing levels.

While there might not be many known applications of CDT's to the process industry, there are a number of well known application of decision trees in statistical applications. The use of trees in regression dates back to the AID (Automatic Interaction Detection) program at the University of Michigan, by Morgan and Sonquist in the early 1960's. In 1984, *Breiman et. al*, published their work on tree methods in classification, Classification and Regression Trees (CART), and brought tree classification methods into a respectable mathematical and statistical framework. They have applied classification tree's successfully to medical diagnostic applications, an ozone classification project and other complex systems.

The general classification problem is as follows: Measurements are made on a case (*as described in Section 3.3.1 above*). Based on these measurements, we either want to predict which class the media it is in, uncover the mechanistic structure of the problem, or both. For the Helios Media manufacturing system both objectives are appropriate. The team would like to be able to predict which of the three classes, defined above, the recently coated media will be in. This information can be used to adjust or correct the processes and materials on subsequent processing days or be used to group the media at the time of coating and decide whether to continue with further value-added activities. In addition, the team would like to gain an understanding of what variables or interactions of variables drive the physical and chemical phenomena.

While both these objectives are important, they play two different roles in improving the manufacturing system. The first, developing an accurate classifier, is reactive process improvement strategy. It accepts that there can be three or more classes of media from excellent to bad and helps to improve a weak process. The second, developing a mechanistic understanding of the system, is a proactive process improvement strategy. A fundamental understanding of the raw materials and manufacturing processes can lead to better process controls and enlarged process capability. It can lead to a manufacturing system -- materials, processes, and people, that always produce excellent product.

Saraiva notes that conventional classification procedures, like multivariate analysis, are aimed at simply estimating y for a given measurement vector **x**. The solution is a given point in the measurement space *X*. "In the types of problems we wish to address decision variables behave as random variables, and there is always some variability associated with them. No mater how good control systems happen to be, in reality we will always have to live with ranges of value for the decision variables (concentrations, flows, etc.), eventually bounded within a narrow, but not null, operation window."[9] Given the fact that we have to operate in a given zone of the measurement space, also known as the decision space, final solutions found by conventional approaches may be sub optimal even if we could develop a perfect mathematical model.

3.4.4.2. Classification Decision Tree Construction

Classification decision trees, also known as binary decision trees, is a sequential method to predict the quality value (or corresponding conditional probabilities) that is associated with a particular measurement vector, **x**. The quality outcome and measurement vector for each case ((**x**, Q) pairs)) from past experiences are assigned to a learning sample *L*.

---

[9] Saraiva, Pedro M. Data-Driven Learning Frameworks for Continuous Process Analysis and Improvement, (MIT Ph.D. Thesis, 1993)

The tree is constructed by repeated splits of *X* into two descendant subsets, beginning with *X* itself. The idea is to select each split of a subset so the data in each of the descendant subsets is purer than the data in the parent subset. This procedure is repeated until, after the last split, vector **x** follows a branch of the tree that leads to a terminal node, labeled with a particular **Q** value and/or set of conditional probabilities, which provides the Q(**x**) and/or the probability that Q is a member of a class given the value of **x**. The idea of building a tree involves three decisions:

- The selection of splits (or tests to be made at each node);
- The decisions or criterion when to declare a node terminal or to continue splitting it; and
- The assignment of each terminal node to a class.

Breiman et. al (1984) put it quite simply, "The whole story is in finding good splits and knowing when to stop splitting." In the examples of CDT's given in the literature by *Saraiva* and *Breiman,* these researchers where able to select a smaller subset from the total possible number of decision variables in **x** to be used in construction a tree. These variables were picked because related studies suggested they had predictive power for the question on hand or because of other statistical tests such as paired T-tests or chi-square tests for independence.

3.4.4.3. Using Decision Trees to Gain Mechanistic Understanding

What I found particularly attractive about using CDT's was it was not necessary to make any prior assumptions about the probability distributions of the quality outcome Q, or the decision variables **x**. This was quite helpful for the individual quality parameters of the

Helios media fit a variety of continuous and discrete probability distributions including normal and poisson. The measurement data **x**, also fell into a number of data types; categorical and real-value data, and distributions. We decided to include all the 100 or more decision variables that could measured, categorized or ranked as possible candidates variables. CDT splitting techniques would be used as a variable selection scheme rather than statistical testing or a priori knowledge. By including all these factors, CDT could be used to look at interactions effects and not just the main effects on system performance.

The result of the classification study, (*See section 3.3.2*) indicated that there might more than one performance objective for the Helios System. Ideally, film media should be a good performer in all environments and age-in within 24 hours after coating. The CDT methodology can be used to handle complex system with multiple performance objectives. However, this appeared to be an ambitious first attempt at using these techniques. Instead, we decided to focus on improving image quality first and worrying about the variability in media aging later. The number one priority for our manufacturing group during this time frame was to make good quality media which did not exhibit image performance problems in hot and dry environments.

Poor image performance in hot/dry conditions could be characterized by a single quality measurement: the percent of ragged or misshapen pixels or pixel units (also known as "mottle") across the image. When this measurement, called Q_{1hd}, was less than or equal to 6 (on a scale of 1 to 10), the image quality was considered "poor". When the media did not perform satisfactory for mottle in the hot/dry condition, it often had an unsatisfactory number of black spots (residual carbon) and appeared hazy or milky to the naked eye. If the media was to have "poor" performance in hot/dry conditions, it usually appeared before or by the $2T$ test point.

There were about 171 cases in the learning set *L* -- some of these cases represented a full day of production while others represented one roll of coated media. While it was desirable to have 200 or more case in the historic database, this was adequate to get started. Using SAS, SYSTAT, or Microsoft Excel, we created scatter plots of our quality outcome Q_{1hd} of all 171 cases against each of the measured decision variables $(x_1,x_2,..x_n;J)$ where J is the class distinction of good or poor. That amounted to 100 or

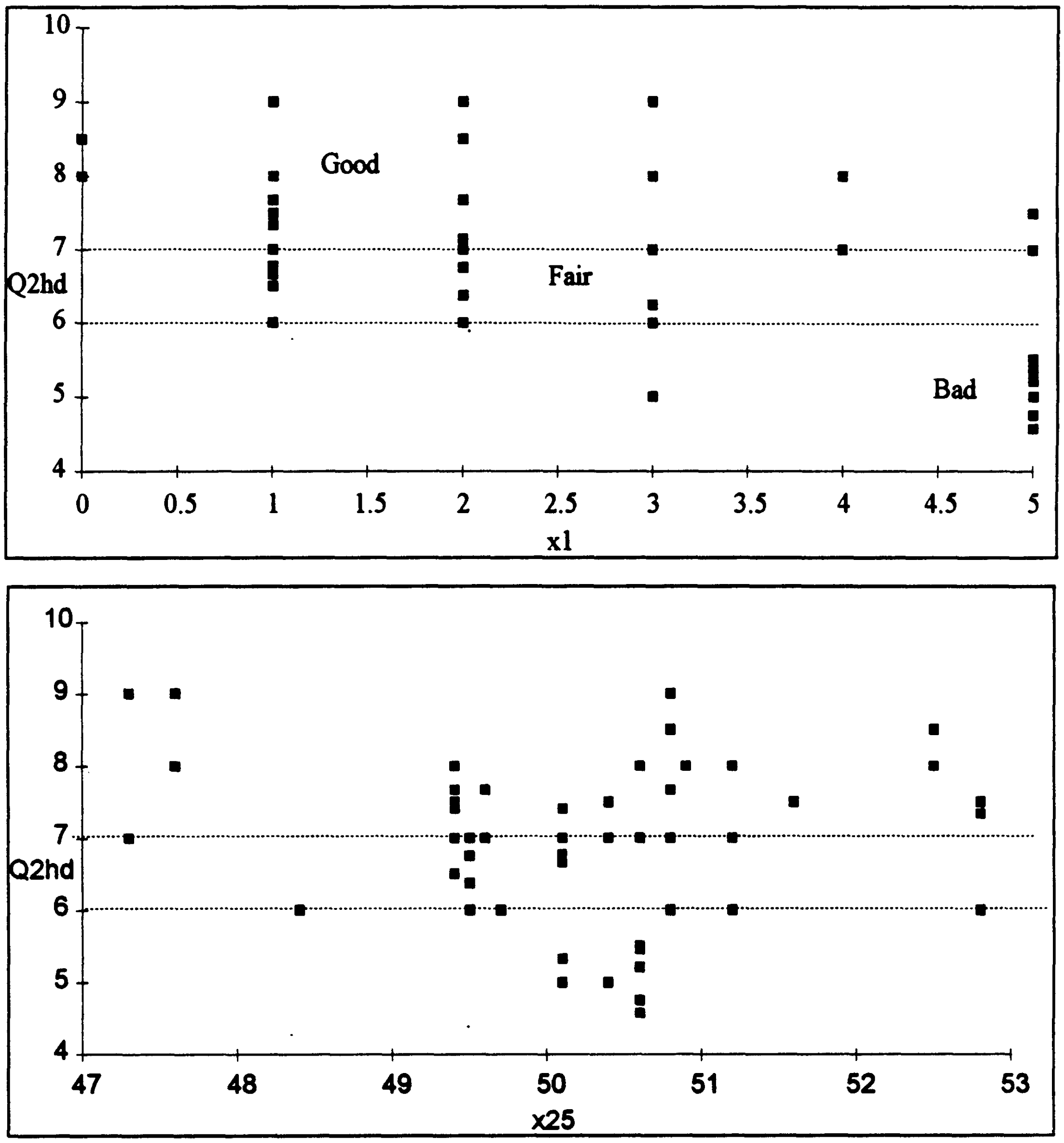


Figure 3.6: Initial Scatter Plots

more scatter plots, each plot containing ninety data points (one for each case). In some situations, there were measurements of decision variables that were missing; however for each case the class label (good or poor behavior in hot/dry conditions) was present. For some of the scatter plots, no clear mutual dependency relationship could be found. For others, a strong pattern was present. After creating the initial scatter plots, we decided to reduce the number of "cases" to 79, which represented cases with 2 independent measurements of each quality attribute.

For each scatter plot there was a best split. Then we compared the *N* best single variables splits and selected the best of the best. This can be done manually by visual inspection (counting the number of good and poor cases in each region) or by using a maximizing criterion. The best split should have the fewest number of cases which are misclassified. We want to select splits that minimize the overall impurity of the binary tree. Once we develop a decision rule, we should test that rule on subsequent cases whose correct classification has been observed. Saraiva (1993) gave an expression for the criterion that can be used to select which test to perform at teach of the nodes of the decision tree which provides the highest information gain at each split. This test is considered to provide the best allocation of examples throughout the resulting children nodes. For the two class problem (good versus poor performance in hot/dry conditions), we began to build the decision tree. The splitting procedure recursively partitions the measurement space into rectangles, such that the populations within each rectangle become more and more class homogenous.

Ideally, we would like to stop the splitting process when the nodes are "pure" (i.e. only contain good or poor cases but not both). These pure nodes are considered terminal nodes. A node could also be considered terminal if one class is clearly dominant (e.g. $p^{est}(Q=j|t)>0.8$). In any case, it is not prudent to continue splitting when the node contains less than five examples/cases. At that point, the terminal nodes were classified as good, fair, or bad. Media in the bad category was scrapped. Media in the "fair" category could be released "conditionally" if circumstances warranted it. There were some branches in the tree where no class was clearly dominant and there were more than five cases with that node (refer to Figure 3.7. below). These nodes were singled out for further investigation.

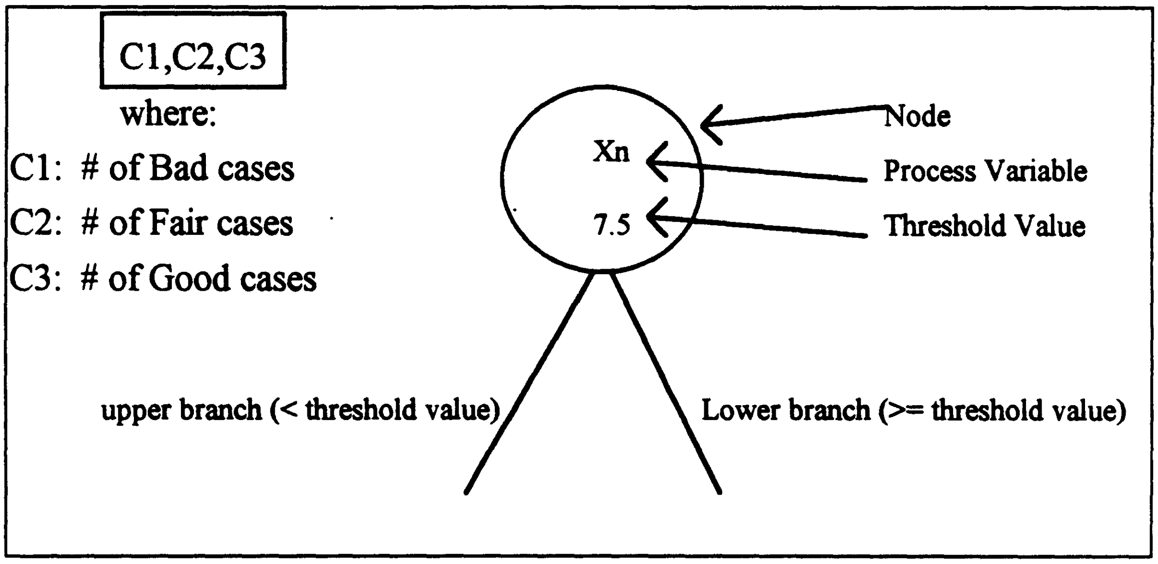


Figure 3.7a: How to read Classification Decision Trees

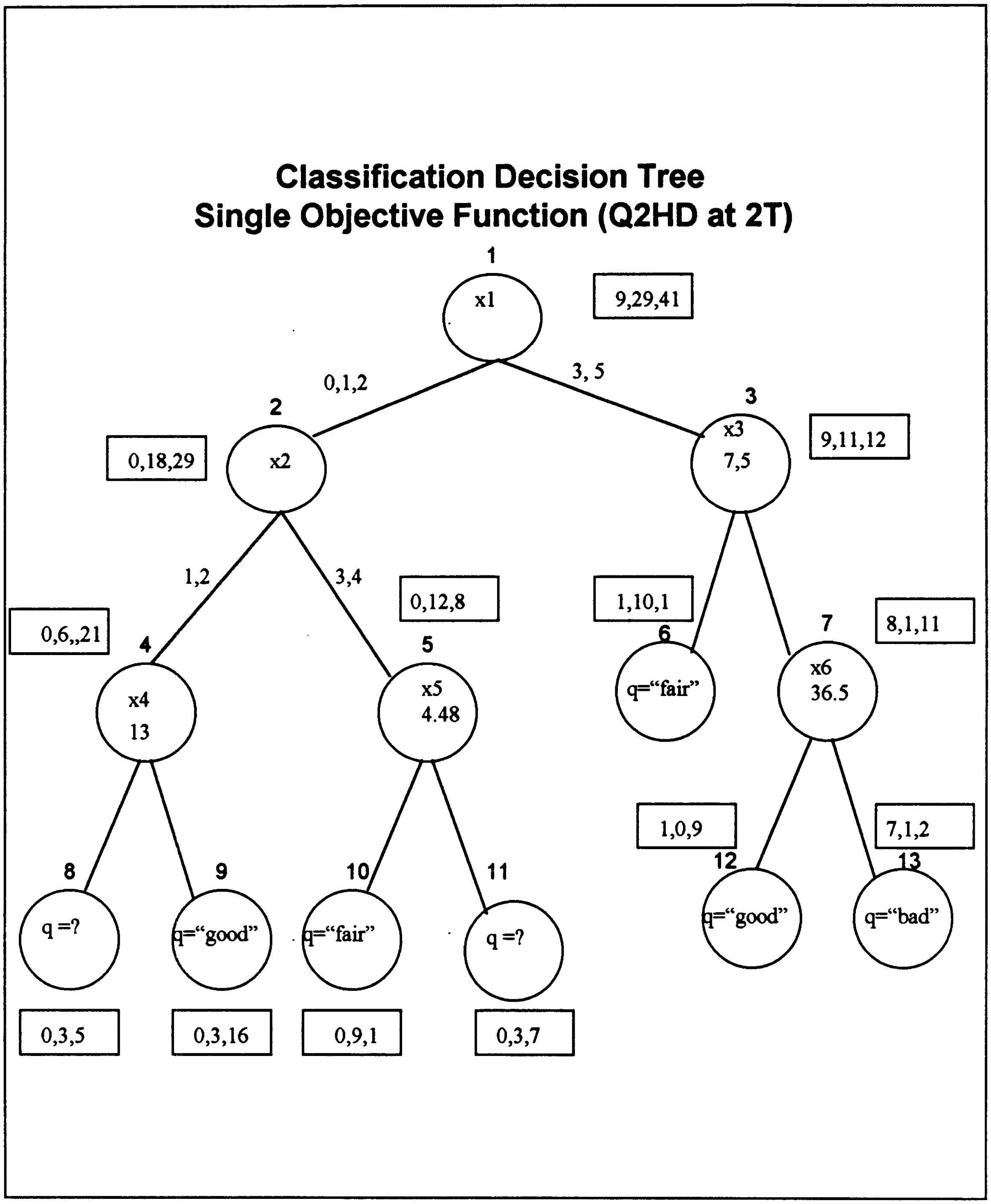


Figure 3.7b: Classification Decision Tree - Single Objective Function

The quality measurement Q_{2hd} was made at the 2T interval. At the parent node (node 1), only 51% of the product was considered good. If we follow the sequential decision rule:

$$x1 = 0, 1, \text{ or } 2; x2 = 1 \text{ or } 2; x4 >= 13$$

then 84% of the cases in this zone (node 9) are "good". A different sequential decision rule also leads to a node (node 12) where 90% of the cases in the decision space were good. All 9 of the "bad" cases were accounted for by nodes from the lower or right hand branch emanating from the parent node. When we re-tested many of the cases at $T>10$, a large percentage of the "fair" cases recently coated had degraded and were no longer acceptable for external customer use.

Both Saraiva and Breiman recommend that initial tree, T_{max}, be "pruned" to build gradually simpler trees, by local detection and removal of unimportant nodes. The formal learning methodology that I followed was developed by Saraiva (1993) and is outlined below.

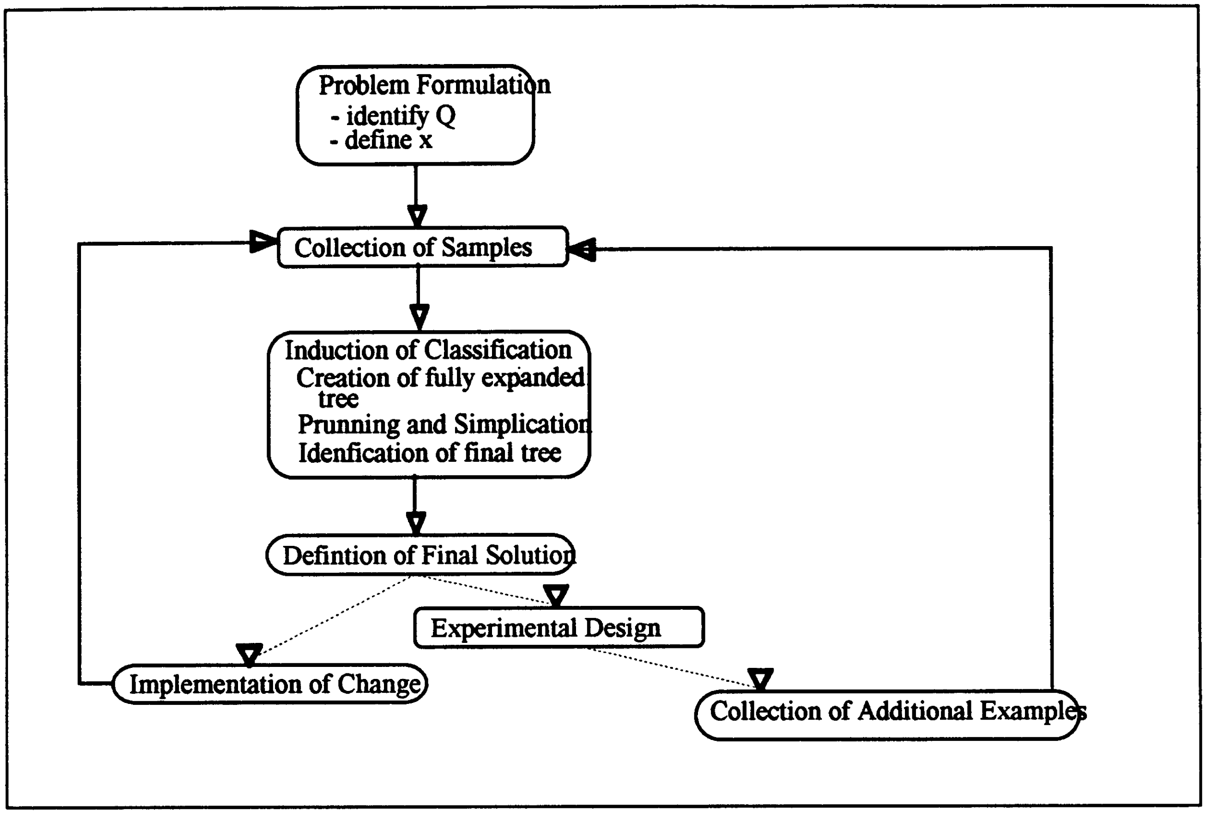


Figure 3.8: CDT Learning Methodology adopted from Saraiva

3.5. Identification of Critical Variables

The results of this attempt at CDT's, focused on a single performance objective Q_{2hd}, was useful in identifying which variables or interactions between variables strongly effected Helios systems performance. It suggested that in order to be in a good zone of the decision space, we had to carefully select combinations of raw materials for certain properties or attributes. This was particularly true for the key layers of the system, and another layer (A) which aided in formatting the media.

While the induction of classification trees did not produced easy to follow supervisory rules that could be used on the manufacturing floor, CDT's and other statistical analysis tools helped highlight areas for further investigation. For instance, we were generating sets of gross measurements that could be made on a given raw material or the resulting fluids. Typical measurements included pH, viscosity, percent solids, etc. For a few layers, like the Carbon and Release, unless the resulting fluid was grossly out of specification, these aggregate properties of the fluids or the raw materials failed to provided insight into how that given component would perform in the system. A given batch of raw materials tended to behave in the system as mechanically weak or strong. While we could categorize or rank these batches of material as "weak", "medium", "strong", this knowledge was based on prior history, not on some characteristic of the material that we could measure and test for explicitly.

In addition, we had focused only on one performance objective for the system. This was based on feedback from the customer that a performance problem in a hot/dry environment produced catastrophic failure. Therefore, if we could minimize the chance of producing media that tended to have hot/dry performance problems, we could increase the manufacturing yields and better satisfy the customer. However, if we selected materials and coating conditions that favored making media with no hot/dry performance problems, we might produce a system that would have unfavorable performance in the other two environmental conditions. This implied there could be value in repeating this exercise for each of the quality outcomes in all of the operating environments.

The construction of a learning data set, (within Microsoft Access) and the subsequent analysis was the framework for building a learning organizations. The results of this first time through the PDCA cycle allowed the group to identify:

- A set of guidelines to make the current product that minimized the chance of producing media with a hot/dry performance problems;

- Areas for further investigation both within the laboratory and on the full-scale manufacturing line; and

- A set of multiple performance objectives to gauge improvements to the existing media product or provide guidelines for creating a new version of the media product.

The next step in the learning process is to use this framework to build a more robust product and manufacturing system.

4. Gaining Process Understanding for Complex Systems

I have suggested that the media team needed to emphasis historic operating data to gain process understanding of the Helios media manufacturing system. The use of standard univariate and multivariate analysis, Pareto diagrams, and Classification Decision Trees provides a useful structure for identifying and organizing data that contributes to process understanding. We discovered that there was no simple first principle model or simple empirical model that could be used to drive Helios system performance. However, it might be possible to develop and validate a set of knowledge based rules to ensure that the resulting media performed satisfactorily in all environmental performance conditions.

Our initial work focused on a single performance objective for the system. While this was useful in *building a learning foundation*, the analysis of system performance indicated that this is a multi-objective system in which there could be conflicts between the best zones of the decision space associated with each different Q_i performance objectives. In this system it is most desirable to operate in a zone of the decision space where the outcome of all y_i 's are "*good*". If this is not feasible, we must be willing to establish priorities for the product and make the appropriate trade-off between performance, customer satisfaction, and operating costs.

4.1. Increasing the Complexity -- Multiple Performance Objectives

It is feasible to extend our learning methods to include multiple performance variables. However, I suggest that the 15 to 30 possible quality outcomes $Q_i(s)$ measured each at 4 standard time intervals as mentioned in *section 3.3.1* might be too numerous to deal with in a meaningful way. Additionally, a number of this quality outcomes were not independent of each other but highly correlated. My first preference was to try to reduce the number of Q_i to the smallest set of independent variables available.

For example, there are two image quality measurements that appear to be highly linked, Q_{1hd} and Q_{4hd}, and these measurements are made in each set of environmental conditions. This was apparent from the graphical analysis of these quality outcomes as a function of time as well as from standard statistical correlation. The correlation coefficient (*r*) of Q_1 vs. Q_5 or Q_3 vs. Q_4 measured at the same time interval was usually quite good. For example, for Ph3154 through Ph3218 at 2*T*, the correlation coefficient r was $r = 0.85$ for Q_{1hd} to Q_{5hd}. Using this technique, we could reduce the number of quality variables to 3 to 5 meaningful measurements for each time interval. The danger is that many of these quality measurements are categorical and highly subjective, and slight differences in measurements can drastically effect the correlation.

We will gain the most knowledge by including all the performance measures in the analysis. However, attempting to perform multi-objective optimization with 15 or more quality measures each evaluated at four (4) standard time intervals, and 100 or more decision variables absolutely requires a powerful PC or mainframe based CDT package, statistical analysis package, and relational database. While we had SAS, Excel, and Access available at Norwood, we could not find a package that could handle the number of decision variables or multiple decision criteria.

Another concern was the that in the Helios Media manufacturing system, there was a small number of cases in the learning set that had simultaneously "good" q_i values in all environments soon after coating. These cases represented less than 10% of the total cases available. If we *relax* one of the constraints on the system -- the media should age in within 2*T* periods of coating, then the number of cases that had all "good" values increases. In this situation, we would look only at the final quality measurements (after the media had aged-in), and just a few critical measures are needed to evaluate to determine if performance is "good", "fair" or "poor". This procedure greatly simplifies the problem, but it neglects the effect that the lag-time has on operating cost, run planing, scheduling, and inventory.

4.1.1. Extending Decision Trees to Multiple Objective Systems

In order to gain the most information from the historical operating data, we recognize the need for a simple to use learning methodology that takes into account the cost of doing business. I compromised and looked at a limited set of performance measures at two key time intervals, $2T$ and $4T$ periods after coating. Saraiva (1993) extended the basic CDT methodology to handle multiple performance objectives. The decision space remains the same as in a single objective situation, but the number of objectives **Y** increases and the performance criteria must include all of them. In order to get started, there are a number of steps that involve the decision makers:

- Establishing the priorities and trade-offs that must be made between these performance objectives.
- Ranking the P objectives in increasing order or relative importance and provide the minimum acceptable operating window for each decision variable.

In addition, Saraiva recommended that we identify the minimum acceptability criteria or constraints in the performance space that must be satisfied despite of how good or bad the corresponding performance of the other objectives might be. In this manufacturing system, it was highly desirable that we minimize the possibility of producing media with "poor" hot/dry performance since this resulted in product that could not be sold to the customer. The major trade-off was between making media that was weak at the time of coating and took a long and unpredictable period of time to age-in versus media that aged in quickly but suffered from a hot/dry performance problem. There are real costs involved in holding inventory for an undefined period of time as we wait for the media to age in. The team could live with some variability in aging but not as much as we were currently experiencing *(see Figure 4.1 . and Figure 4.2. below).* In the last 10 production campaigns, the number of periods for the media to have acceptable performance in Hot/Wet conditions varied by as many as 22 time periods. Therefore we might want to set a criteria that no more than say 10% of the system will have a Q_{1hd} value of "poor".

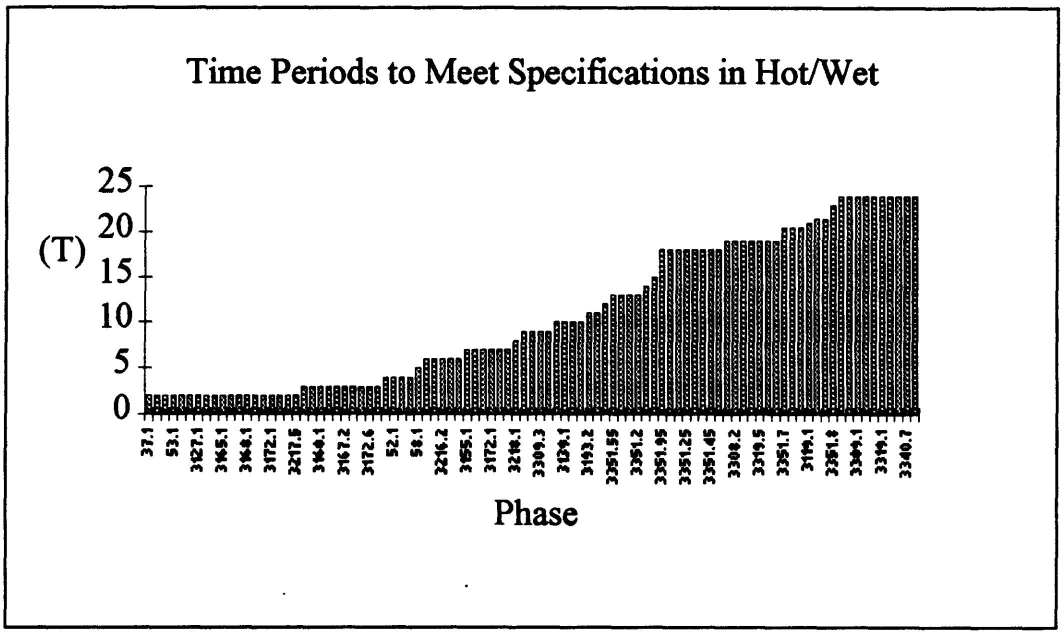


Figure 4.1: Time Periods (T) to Age-in in Hot/Wet

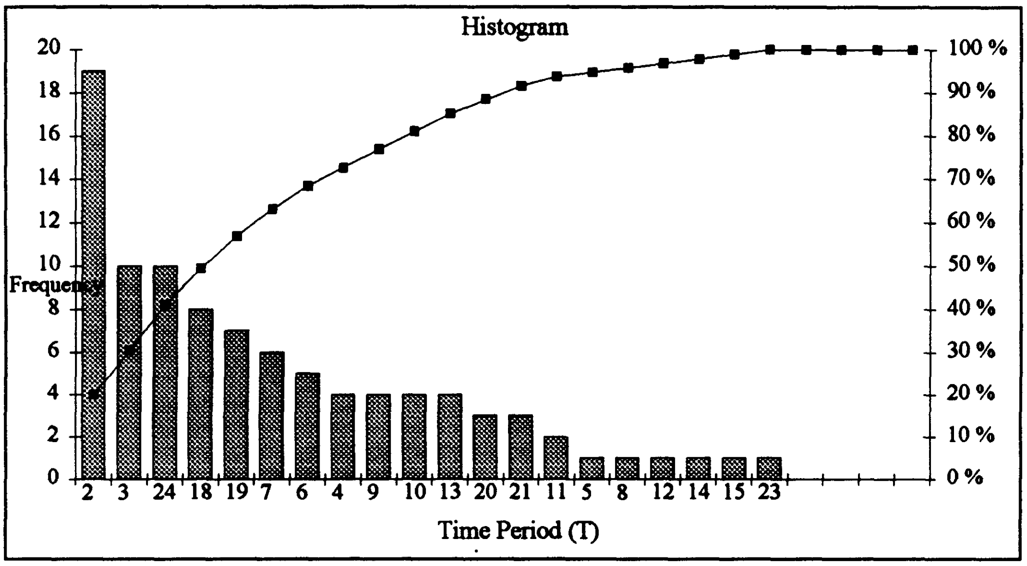


Figure 4.2: Histogram of Frequency of Time Periods to Age-in in Hot/Wet

There is an alternative approach to increasing the number of performance objectives. We could induce a separate decision tree for each of the individual performance objectives. In this case we would have at least two different trees, one for each set of extreme environmental conditions -- hot/wet and hot/dry. If we were lucky, each of the decision tree's would produce overlaps in the same rectangular operating zones. If conflicts arose between these solutions, we could apply the same type of trade-off analysis as in a multiple objective system. The advantage to this multi-step approach is that without CDT software that could handle multiple performance objects, this was computationally simpler to manage.

The induction of a CDT for Q_{3hw} produced a number of terminal nodes that were not pure. There were two conclusions we could glean from our attempt to build this tree. First, that there seemed to be a shift in the performance of the system with time. That is, the product appeared to take longer to age in for runs coated in the second half of the year. Unfortunately, we could not pinpoint this shift to a single change in process conditions or raw material batches. There were too many raw material batch changes to find a "clean split" in performance. Second, we suspected that there were interactions between two of the layers of the media laminate. Each of these layers had a different main ingredient where a number of batches of raw materials were tried in this time period. To draw any further conclusions, we needed a much larger number of cases (one to two years of production) to produce CDT's that were meaningful.

In the single hot/dry as well as the hot/wet classification tree's, the analysis indicated that there could be an interactive effect between various layers of the system which if balanced would produce good product. This result was a bit surprising. The original intent of the product developers was to design a product that was able to tolerate to raw material changes within a certain specification limit. However, the product development work was done using a rather homogenous set of raw materials and at fairly low volumes.

The symbols $R_1, R_2 ... R_n$ will be used throughout the rest of this chapter to represent the key ingredient/ raw material required to make a fluid which forms a layer of the Helios media. The first "batch" of R_2 raw material used to make one layer of the media laminate lasted for most of the development effort and into early production runs. Similarly, the early batches of R_1 material, the main constituent of a different layer of the media laminate, also appeared to be homogenous, coming from a limited group of raw materials processed around the same time interval.

Over the course of the product introduction, the R_1 "make/blending" process had been improved -- producing a material that appeared to have a more uniform distribution. Also, a main attribute of the R_2 material, was not consistent on a batch to batch basis. The effects of these changes in raw materials on the resulting image properties could be more carefully studied using designed experiments.

The CDT investigation also revealed that if the material properties of a key ingredient in the (A) fluid had changed or degraded (see node 3 of Figure 3.7b), the resulting media would fail regardless of which combinations of R_1 and R_2 were used. While it was difficult to control this 'gross' macroscopic property of the raw material, it was a simple matter to set up acceptance tests to ensure that the raw materials selected for use in a production run meets the criteria established.

The solutions we uncovered using CDT's were only as useful for decision making as the measurements we could make within the decision space. As a team, we could not quantify what made a R_1 or R_2 layer behave as strong or weak and therefore could not measure that attribute or property directly. However, the use of CDT's did suggest that we could learn from historic operating data to develop a set of decision rules that we could use to plan each production or test run. The data within the learning set could aid in determining if a particular batch of the raw R_1 or R_2 caused the system to behave mechanically weak or strong system.

4.2. Developing a Rules Based Approach to Improve Quality

A number of researchers (Saraiva, Stephanopoulos, and separately, John D. C. Little[10]) suggest there is value developing models that are simple to use at both the management level and plant floor supervisory level. A simple model or set or rules that are easy to understand and validate stands a much better chance of being used to improve both technical and business decision making. The use of knowledge based rules or learning is becoming more common in business situations through the use of artificial intelligence applications. Many expert system attempt to incorporate the knowledge of a single expert or group into rules that can be followed by an analyst, manager, or other non-expert users. By using CDT's we could develop a set of knowledge based rules in lieu of a first principle model that provides guidance for both management and manufacturing to ensure that the product continually meets the customer's performance expectations.

The Classification Decision Tree's we had constructed were based on knowledge derived from the historic operating data rather than a parametric model of the process. While it is ultimately useful to gain a more fundamental or explanation based understanding of the processes, the knowledge we have gained from past runs can be incorporated into the group's decision making activities. Until then, the terminal nodes of the CDT's which

---

[10] John D. C. Little, "Are There "Laws" of Manufacturing?", Manufacturing Systems: Foundations of World-Class Practice. Joseph A. Heim and W. Dale Compton, Editors; (National Academy Press 1992)

provide the highest probability of "good" product are particularly appealing. Product produce by constraining the operating variables into this rectangular zone of the decision space has a greater than 80% of being good as opposed to 51% under the previous operating conditions *(see node 9 and node 12 of Figure 3.7a)*. This was confirmed by subsequent runs of the product using the decision rules developed in section 3.4.4.3.

In the Helios system, the split values or threshold values x_i, are either categorical, discrete, or continuous operating variables. In many cases, when x_i represents a flow, temperature, or pH, etc., the variable can be directly manipulated or controlled by the technicians or floor supervisors. In other cases, when x_i represents properties microscopic properties of the materials which are harder to measure and characterize. While we cannot directly control these variables, we might be able to actively select materials for a number of these attributes.

The multivariate statistical analysis and CDT learning method indicate there were raw material and fluid interactions that affect system performance. Based on our current understanding of the system, these interactions are due to properties or attributes of the material that could be tested for or screened for but not directly measured or manipulated. At first blush, this suggests that the odds of producing material that is "good" is a hit or miss proposition. However, the situation was not that grave. The batches of raw materials can be large enough to be used for more than one production run in Norwood. While this type of production methodology might not lend itself to a just in time type of production system, we can use information about past performance to plan or gage each subsequent production run.

The decision trees provide a graphical representation of a set of sequential decision rules which if followed can minimize the probability of producing poor material. The decision rules implied from the CDT analysis required the team to carefully mix and match raw materials based on their ability to adhesively and cohesively fail to each other. This matching of R_1 and R_2 materials can be done based on knowledge of past performance of combinations of R_1 and R_2 incorporated in various runs of media or through test runs on the manufacturing line or maybe using the smaller test coaters in Norwood or Waltham. This approach to product management requires the team to modify their methods of both run planning and materials management (*Refer to section 5.1.2*).

Ideally, the CDT learning methodology should not require a large number of a priori decisions. By having to "benchmark" the performance of combinations of batches of raw materials prior to a large production run, a significant amount of a time, expense, and testing is incurred. A strength of the CDT methodology should be that it does not rely on having to formulate an explanation of system performance that is founded in the chemistry and mechanics. However, until the Helios team can determine which attributes of the raw materials and fluids are critical in controlling systems performance, it is useful to continue chemical and material analysis activities which will lead to better understanding of the underlying chemical and physical mechanisms. The CDT analysis and other statistical modeling helped to highlight the weakness in the current raw materials testing and characterization processes.

At this point in time, we could use our knowledge of the system and the analysis of the historical operating data to hypothesize a mechanism of why the system performs the way it does in each environment. This fundamental learning was necessary to be able to re-engineer the product or manufacturing processes to increase system performance as well as increase the manufacturing latitude. The set of run rules we developed based on the results of the Tree's help to significantly improve the yield of "good" product. We wanted to test the idea that a rule based approach to production is useful when developing a mechanism or first principle's model is difficult. However, if the team can't directly control for material properties, the uses of run rules are just another step in the PDCA process of gaining a more fundamental mechanistic understanding. One of the best tools available to the team to enhance and build on the learning gained to date was through use of Designed Experiments.

4.3. Validation of Run Rules through Designed Experiments

The execution and analysis of designed experiments allows the user to systematically improve quality and uncover promising zones in the decision space to conduction operations. A "proper" design of experiments (DOE) consists of purposeful changes of the inputs (factors) to the Helios manufacturing process in order to observe the corresponding changes in the outputs (response). We have employed DOE as an integral part of the iterative learning approach in this manufacturing system. The designed experiments allow us to accomplish multiple functions to enhance the group's learning. The first is to validate the "run rules" we have developed which calls for careful balancing of combinations of raw materials. A second is to uncover information about the basic characteristics of the raw materials and fluids A third use of DOE's is to systematically explore changes to the media formulation or structure of the system.

4.3.1. Barriers to Running Designed Experiments

In the past, there have been significant barriers associated with running designed experiments within the Norwood production coating facility. DOE run on the test coater or pilot coating facility provides useful insights into the manufacturing processes, but historically these results have not been easy to reproduce on the full scale coater. This is due to the fact that the scale and technology employed in the test coater is dissimilar to that in the production line. While the semiconductor process industry has invested significantly in building pre-production or pilot facilities that employ the exact same technology and process control equipment as the production fab, that has been very difficult to do in the film industry. At minimum, the width of the web is different and usually of a smaller scale in the pilot facility. In our situation, the web width, coating heads, and drying methods were to some extent different between the production coaters and test coaters.

Most experiments performed on the coating production line had been a one-factor-at-a-time type of experimentation. The group typically selected factors for test based on past experimentation or intuition. There was resistance to running full factorial designs because of the time it takes to switch dispensing tanks, re-mix fluids, or adjust and re-profile ovens. A typical full factorial design involving raw material changes or fluid mix processes could require the use of eight or more dispensing tanks and significantly reduce the throughput of the line. Most of the production equipment in the Norwood line is of an earlier vintage and the tank switches, flow rate changes, and temperature adjustments have to be performed manually. The chance of error is much higher than in a fully automated coating facility and the manual adjustments can be a large source of error.

There are other elements which have also made running DOE's difficult. A primary consideration in evaluating performance is the aging effect we had been experiencing in producing Helios media. It may take many periods before a statistically significant difference in imaging performance is observable. Also, some performance related differences may not appear until the media is run through production level printers in a number of customer environments. This type of testing is difficult to replicate in Norwood and we have had limited success with "total" system verification testing at the hardware manufacturing site (*Refer to Section 5.1.3.1*).

The results of prior production runs indicate that the performance of rolls of media coated contiguously (using the same set of process conditions and fluids) are repeatable. Constantly changing the fluids, flow rates, or oven temperatures tend to upset the stability of the line. However, due to production time pressures, it is rare to be able to coat more than one roll with a given set of experimental process conditions; thus the line never has a chance to fully stabilize to any given set of conditions during the experimentation. Consequently, we have to manage the trade-off between running repetitions of each cell in the designed experiment versus testing a fuller set of inputs.

4.3.2. Planning Designed Experiments

Because of these operational challenges, it takes a significant commitment on the part of the Helios media manufacturing team to run designed experiments. The team has to be very deliberate choosing which factors to test and planning each experiment. Researchers Schmidt and Launsby have developed a number of guidelines for organizing the experiments. They have found one of the most effective approaches to the planning phase is to use the informal "brainstorming" technique.[11] We found this technique to be effective if each member of the team had an opportunity to review the historic operating data in a orderly fashion. The team also employed a more structured brainstorming technique to organize experiments by using the Kepner-Tregoe method for analyzing problem deviations (*Refer to Section 3.1*).

The team used the information from our statistical analysis and classification studies to brainstormed on a mechanism to describe media performance in the different environmental conditions.. The output of these sessions resulted in generating the factors to test and selecting the responses to measure. The members of the team include

---

[11] S. R. Schmidt, R. G. Launsby, Understanding Industrial Designed Experiment, 3rd Ed., (Airforce Academy Press, Colorado Springs, CO. 1991): 1-23.

production, product engineering, process engineering, and materials/fluid operations. In most cases, we tried to keep the planning team small (4 to 10 people) to ensure each member had a chance to participate. We record each idea on a flip chart to ensure each idea is not challenged or dismissed until the brainstorming session was over. When the brainstorming session was over, we critiqued the list and reduced the components into a workable number of ideas. There were usually more ideas to test than time available on either the production or test coaters. Thus, it was important to identify the critical problem areas (from historic data or current customer issues) and focus on this first.

The aforementioned operating challenges influenced the number of inputs (factors) we tested. There was a physical limitation to the number of runs (set of process conditions) that could be changed on a given production day. A two-level orthogonal designed experiment could be completed in one day (coating one or more roll or each run) while a three-level design typically required two days to complete. In many instances, the production coater was run for two shifts, then shut down overnight. This meant the web, dispensing carts, and ovens had to be restarted each morning. Spreading the designed experiment out over two or more production days introduced "day of the production run" as an additional factor. Ideally, we would use "day" as a blocking variable to evaluate the differences between two blocks of experiment.

4.3.3. Conducting Designed Experiments

As indicated earlier, there were three general motivations for running designed experiments:

- Validating a solution or region of the decision space;
- Enhancing mechanistic understanding; and
- Refining or re-engineering the product.

I will address the first two points in this section and talk about product re-engineering in Chapter 5 of this thesis. Of primary importance was the need to corroborate the insights and "run rules" we had received from the Classification Decision Tree data analysis. We relied on historic data to identify critical problem areas. However, using either CDT methods or other learning methods, there is a need to verify or refine the solution using data from outside the original historic learning set. Saraiva and Stephanopoulos (1992) suggest that we can use the output from these statistical learning methodologies to identify the factors and levels to be run in a set of verifying experiments. These experiments should be performed before implementing the run rules or process changes.

Our statistical analysis (both univariate analysis and induction of decision tree's) uncovered three areas to investigate. First, the age or freshness of the fluids appeared to be factor influencing final product performance. Second, changes in oven temperature, especially drying of the R_2 associated layer, appeared to affect final product performance. Finally, certain combinations of raw materials markedly affected product performance. We planned and ran designed experiments aimed at verifying these findings.

4.3.3.1. Freshness of Coating Fluids

Because of Norwood's multiple missions (Helios production, new product development, more traditional film production) there were two general types of Helios production runs; discrete runs were the coater was shut down at the end of each day and restarted in the morning and continuous runs were the coater was run for multiple twenty-four hour periods before a shutdown.

An analysis of the historic data revealed that there was a significant difference between the imaging performance of product at the $2T$ and $4T$ test points when they were coated on successive <u>discrete</u> coating days. The most important input factor appeared to be the age of the fluid at the time of coating. The hypothesis was that use of fresh coating fluids each day would reduce the aging variability we had noted on a day to day basis with a multiple day production run. However, we coat multiple fluids to create the full Helios structure. It would be impossible to test aged versus fresh fluids for the full structure. With the guidance of the materials group, we chose to test only three of the fluids and hold the rest of the process conditions constant.

Experimental Design Strategy: The experimental design is a simple L4 orthogonal array with the two main factors of R_1 type and R_2 type. In addition, the age of fluid A and the fluid containing R_2 is a component of the design (made fresh each day instead of fresh on the first day only) and day is also an uncontrolled factor since we could not complete the experiment on a single day. This type of modified experiment is not atypical of a "designed experiment" in this manufacturing environment. A "new fluid" is a fluid that is mixed early each morning before the start of the production run. All other coating fluids were made up early Monday morning in large batches and consumed over the four day period. These fluids were not refreshed in any way during the production run.

Phases 3243-246					
Run #	R_1	R_2 Fluid	R_2 fluid age	A Fluid Age	Day
1	HMB 326 (+)	Type 2 (-)	fresh	fresh	1
2	HMB 526 (-)	Type 2 (-)	fresh	fresh	2
3	HMB 526 (-)	Type 1 (+)	fresh	fresh	3
4	HMB 326 (+)	Type 1 (+)	fresh	fresh	4

Table 4.1: DOE - Fluid Aging Effects on Product Performance

Selecting the Quality Characteristics: It is very important to select the appropriate quality characteristics or responses to measure. In this instance, we were testing whether the age and type of fluid was responsible for the variability of the product performance.

Therefore we had to measures and analyze quality indicators which would provide that type of information. The best indicators of product "aging" are measures of the systems ability to leave a carbon line or pel on the polyester base that contains the positive of the image. As noted before, most of the quality indicators were not continuous but rather discrete quality data or categorical data.

Data Analysis Methods: Because this experiment combined a two factor (2 level) full factorial along with other components multiple data analysis approaches were required. We used simple graphs as well as more complex statistical techniques such as Analysis of Variance (ANOVA) and or linear regression. It was also impossible to truly "randomize" the runs in this type of continuous process environment.

Conclusions, Predictions, and Confirmatory Tests: The original intent was to try to produce product that both performed well and aged-in uniformly. The experiment that was ultimately run was not optimal for this type of information gathering. Ideally, we should have run and designed an experiment which tested these factors directly. The experiment outlined above, did however, provide the group with information about the relationship between R_1 and R_2 types. The image quality for all the runs was measured in room temperature conditions at $1T$, $2T$, and $4T$ time periods. For the quality parameter Q_{3rt}, the analysis is outlined below.

Q_{3rt}	$1T$		$2T$		$4T$	
Factor	Fratio	P	Fratio / Rank	P	Fratio / Rank	P
R_1 Type	0.526	0.485	14.758 (3)	0.001	34.845 (1)	0.000
R_2 Type	0.526	0.485	17.329 (2)	0.000	1.845 (3)	0.189
$R_1 * R_2$	8.421	0.016	27.391 (1)	0.000	5.979 (2)	0.023
Error (SSE,DF,MSE)	(22.8,10,2.3)		(54,25,2.2)		(30.4,21,1.45)	
R^2	0.468		0.649		0.672	

Table 4.2: Evaluation of Fluid Age on Product Performance - Q_{3RT}

A complimentary media characteristic to Q_{3rt} known as Q_{4rt} was also measured at the same time intervals. Ideally, these two measures should provide very similar information. The results indicate that maybe these two quality indicators were measuring different capabilities of media performance since the rank and magnitude of the effects at $2T$ and $4T$ were quite different.

Q_{4rt}	$1T$		$2T$		$4T$	
Factor	Fratio	P	Fratio / Rank	P	Fratio / Rank	P
R_1 Type	0.355	0.564	23.837 (1)	0.000	8.298 (2)	0.009
R_2 Type	0.050	0.811	16.393 (2)	0.000	8.141 (3)	0.010
$R_1 * R_2$	0.000	0.918	5.119 (3)	0.033	39.955 (1)	0.000
Error (SSE,DF,MSE)	(0.012,10,.001)		(.004,25,0.00)		(0.01,21,0.00)	
R^2	0.043.		0.621		0.727	

Table 4.3: Evaluation of Fluid Age on Product Performance - Q_{4rt}

There were two different R_1 types reflected in this system, HMB326 and HMB526. The most favorable run was with materials that used the HMB326 with the type-1 R_2. This was the only combination of materials which met the specifications for both Q_{3rt} and Q_{4rt} at the $4T$ test period. The HMB326 R_1 was four days old when it was coated on the last day of production along with a fresh make of the type-1 R_2 on the last day of the production run.

While this experiment provided useful information about the performance of different combinations of R_1 and R_2 types, it did not provide much insight into the effects of fluid aging of product performance. The use of fresh R_1 mixes and fresh fluid "A" mixes alone did not reduce the variability in "aging" we had previously observed on a day-to-day basis within a given production campaign. However, this experiment was wildly confounded by the deliberate change of both the R_1 and R_2 lots each day. Ideally, a more structured fluid aging experiment should be performed once production of the existing or new media prototype is moved to the Southern, MA. facility. The team should be careful to remove "production day" as a factor by running both "freshly made" and old coating fluids on a given production day.

4.3.3.2. Verification of Run Rules

The results of the CDT analysis implied there was interplay between R_1 type and R_2 layer type. That is, in order to have a run with satisfactory performance in all environmental conditions, we had to select combinations of R_1 and R_2 batches that are balanced. This run rules requires as a decision factor, a priori knowledge of the behavior of different lots of materials. We believed most of this information could be collected as a part of "raw material lot checkouts" or as part of a larger production campaign.

Experimental Design Strategy: The selection process for raw materials batches would be based on historic operating data (past runs using a particular combination of raw materials) or by running a matrix of combinations of raw materials in a pre-production run or as part of a larger production campaign. Ideally, a pre-production run is the ideal approach since we can test all factors in a single production day. However, we can also learn about the coating process variability if we spread the runs out over multiple days of a continuous coating run. Over the course of three months, we completed a number of these types of R_1/R_2 matrix runs. Many of these runs were simple orthogonal arrays.

Ph 3319	Factor A	Factor B	Factor C	
Run #	R_1	R_2	Process D	Day
1	HMB 913 (+)	R495 (+)	type 0 (+)	1
2	HMB 913 (+)	R495 (+)	type 1 (-)	1
3	HMB 525 (-)	R495 (+)	type 0 (+)	2
4	HMB 525 (-)	R495 (+)	type 1 (-)	2
5	HMB 525 (-)	R226 (-)	type 0 (+)	3
6	HMB 525 (-)	R226 (-)	type 1 (-)	3
7	HMB 913 (+)	R226 (-)	type 0 (+)	3
8	HMB 913 (+)	R226 (-)	type 1 (-)	4

Table 4.4: Designed Experiment (Orthogonal Array) - Ph3319

Ph 3340	Factor A	Factor B	Factor C	
Run #	R_1	R_2	Process D	Day
1	HMB 915 (+)	R 495 (+)	type 0 (+)	1
2	HMB 915 (+)	R 495 (+)	type 1 (-)	1
3	HMB 525 (-)	R 495 (+)	type 0 (+)	2
4	HMB 525 (-)	R 495 (+)	type 1 (-)	2
5	HMB 525 (-)	R 226 (-)	type 0 (+)	3
6	HMB 525 (-)	R 226 (-)	type 1 (-)	3
7	HMB 915 (+)	R 226 (-)	type 0 (+)	3
8	HMB 915 (+)	R 226 (-)	type 1 (-)	4

Table 4.5: Designed Experiment (Orthogonal Array) - Ph3340

By combining these two experiments *(see tables 4.4 and 4.5)*, we also have a factorial design that is "blocked" across two different production campaigns (*see table 4.6. below*). We deliberately chose to repeat these combinations of raw materials in two successive coating campaigns. The intent was to learn more about the repeatability of the coating processes on a run to run basis. It is important to note that this experiment is not completely "clean". That is, while all the major raw ingredients in the R_1 and R_2 fluid mixes from run to run were identical, there are subtle changes in raw materials in other fluids and layers. Since the fluids are mixed "fresh" for each production campaign, the mixes are not identical. While these runs provide useful data on run-to-run variability, there are factors that are confounded (and will always be so since each production run is a "unique event).

Ph 3319, 3340		Factor A	Factor B	Factor C
Run #	R_1	R_2	Process D	Run
1	HMB 525	R495 (+)	type 0 (+)	1 (+)
2	HMB 525	R226 (-)	type 1 (-)	1 (+)
3	HMB 525	R495 (+)	type 0 (+)	2 (-)
4	HMB 525	R226 (-)	type 1 (-)	2 (-)

Table 4.6: Designed Experiment (L8 Orthogonal Array) - Blocked by Campaign

The image quality of the run was measured all three environmental conditions at various periods from the time of coating up to 15*T* periods. The initial results (2*T*) from the Ph3319, Ph3340 indicated that there was only subtle differences in performance between HMB 5XX R_1 and HMB 9XX R_1. The upstream supplier had completed a process equipment change that effected all R_1 blended after HMB 5XX . While this change by itself should not have affected the performance of the material in the product, we had observed an ongoing shift in performance from lots HMB 3XX through 12XX. The lots are blended in sequence.

To test this hypothesis, we completed a run that examined R_1 (4 levels), process D type (2 levels) and Fluid A raw material batch (2 levels) as factors. A design matrix *(refer to Table 4.7. below)* displays the combinations in the experiments -- 16 runs are required (4x2x2). Within each R_1 type, an L4 of the other two factors are nested. Unlike many of the designed experiments described in this section, this run was started and completed on a single production day.

Data Analysis Methods: The above five experiments were analyzed using ANOVA and multiple linear regression techniques. While most of the experiments started out as perfectly balanced orthogonal arrays, we could not always finish the runs as planned. For the experiment described as Ph3319, only 7 of the 8 test combinations were actually run. The advantages of full factorial designs are orthogonality, no aliasing concerns, and all the main factors and all interactions can be evaluated.

Ph3351	Factor A	Factor B	Factor C
Combination	R_1	Process D	Fluid A
1	HMB 524	type 0 (+)	0 (+)
2	HMB 524	type 0 (-)	1 (-)
3	HMB 524	type 1 (+)	0 (+)
4	HMB 524	type 1 (-)	1 (-)
5	HMB 1207	type 0 (+)	0 (+)
6	HMB 1207	type 0 (-)	1 (+)
7	HMB 1207	type 1 (+)	0 (+)
8	HMB 1207	type 1 (-)	1 (+)
9	HMB 1209	type 0 (+)	0 (+)
10	HMB 1209	type 0 (-)	1 (+)
11	HMB 1209	type 1 (+)	0 (+)
12	HMB 1209	type 1 (-)	1 (+)
13	HMB 1209-2	type 0 (+)	0 (+)
14	HMB 1209-2	type 0 (-)	1 (+)
15	HMB 1209-2	type 1 (+)	0 (+)

Table 4.7: Designed Experiment (L16, Orthogonal) - Ph3351

<u>Sample analysis of Hot and Dry Performance (Ph 3319):</u> The image performance of the run was measured at the $2T$ to the $15T$ time periods. In this run, 3 factors were tested -- R_1 (2 levels), R_2 (2 levels), process D type (2 levels). At the $2T$ test period, the run looked remarkably consistent (no observable difference in the measurements) for all major quality

indicators except Q_{5hd}. Because this run was unbalanced (only 7 of the 8 possible combinations were completed),this evaluation was made by performing an weighted means model analysis of variance test in SYSTAT using the three main factors; R_1, R_2, and process D type. We define the test hypothesis as:

$$H_0: \quad \mu(+) = \mu(1)$$

$$H_1: \quad \mu(+) \neq \mu(1)$$

While we can set any α such as $\alpha = .05$, the software program actually computes a P value and F ratio which can be used to fail to accept H_0, or accept H_1. As a rule, we will fail to reject the null hypothesis if $P > 0.05$. For the quality indicator Q_{5hd}, the test generated an F-ratio=10.8, P=0.000 for $F(1-\alpha, 5, 18)$, so further evaluation using that response variable was done. A Multiple Linear regression model (MLR) analysis with three factors R_1, R_2 type, Process D type revealed an $R^2 = 0.830$ with P=0.000. By performing a stepwise general linear analysis for all factors except the 3 way interaction (R_1*R_2*Process D) we achieved an $R^2 = 0.805$ and R_1 type as the only remaining factor (all other variances were pooled).

The average Q_{5hd} or Q_{5rt} value for R_1 type 913 just met the production specification. The average value for the type 525 R_1 exceeds the specification by 10%. While 10 percentage points above the minimum value set in the specification may not seem significant, 20% points above the minimum acceptable value is the maximum value we have achieved with this product to date.

By the 15*T* point, we observed a real shift in performance. A number of quality characteristics or response variables (Q_{1hd}, Q_{5hd}, and Q_{6hd}) all tested for significant effects using the weighted means model. analysis of variance with $P <= .01$ as the threshold for rejecting the null hypothesis. I performed a stepwise general linear model analysis using all factors except the 3-way interaction of R_1*R_2*Process D for each of the above quality indicators. The minimum tolerance for entry in the model =0.01, with a forward step-wise alpha-to-enter of $(\alpha) = 0.15$ and a alpha-to-remove of $(\alpha) = 0.15$. During this time frame, the Technical Evaluation Lab introduced new quality measurements standards for non parametric quality indicators of 1-to-5, with 1 being the best. The replaces the old scale of 1-to-10 with 10 being the best.

For the quality indicator Q_{1hd}, the stepwise modeling generated a subset model with three predicators of quality: R_1 type, R_2 type and R_2 type*process D type (with an $R^2 = .931$, Adjusted $R^2 = .920$, and P=0.000). The R_1 type had the strongest effect on Q_{1hd} performance (with T=-15.72 and P(2 tail) =0.000). A similar analysis for the response variable Q_{5hd} indicate that the same factors as in the *2T* period effect performance; R_1 type and R_2 type, with R_1 type having the strongest effect (with a T=12.81 and P=0.000).

15T Test Period SOURCE	Rank Q_{1hd}	Rank Q_{2hd}	Rank Q_{6hd}	Rank Q_{5hd}	Rank Q_{8hd}
R_1	1			1	1
R_2	3	2		2	
PROCESS D					
$R_1 * R_2$		3			
R_1*PROCESS D	2				
R_2*PROCESS D		1	1		
R_1 *R_2*PROCESS D					
adjR^2	0.920	0.325	0.682	0.882	0.348
SSE	0.282	0.335	0.592	0.057	0.673
Error (SS,DF,MSE)	(1.59,20,0.08)	(2.25,20,.11)	(7.7,22,0.35)	(0.069,21,.00)	(10,22,0.45)

Table 4.8: Analysis of Designed Experiment (ANOVA) - Ph3319

Analysis of Hot and Dry Performance (Ph 3340): We performed a similar analysis on the performance of 3340 in the hot/dry environmental conditions. This run was perfectly balanced and it was possible to perform a standard fully factorial (M) ANOVA. The quality response variables were analyzed at the 2*T* through 13*T* periods. The same three factors as in Ph3319 were tested. ANOVA was utilized to get a statistical representation of important factors. Testing procedures for significant effects are outlined below:

Step (1):	H_0: $\mu(+) = \mu(1)$
	H_1: $\mu(+) \neq \mu(1)$
Step (2)	$\alpha = 0.05$
Step (3)	Calculate MSB, MSE, Fo
Step (4)	Fc=F(.95,v1, v2)
Step (5)	Is Fo>Fc?, conclude H_1 (i.e., factor is significant and belongs in the prediction equation).

Steps 1-5 can be completed by observing the F-ratio and P value generated by SYSTAT for each effect. However, since the preciseness of the P value is based on the normality of the response, it was useful to examine average effect plots.

At the 2*T* test period, an ANOVA for many of the response variables generated $R^2>0.8$, for the quality measurements of (Q_{1hd} to Q_{4hd}) -- however there were no factors for those response variables with effects having an $P<0.05$. For Q_{5hd}, $R^2=0.995$ and the effects had a P value, $P<=0.05$. The most significant effects listed in order of rank are listed in Table 4.9 below. This result differs from Ph3319 at the same period when R_1 type only was a significant factor. The analysis was redone for the 13*T* time period. There was a difference in the rank of the effects for each response varible between 2*T* and 13*T*. Additinally, for the attributes Q_{1hd} and Q_{5hd}, both runs by $T>=13$ indicated that R_1 was the major factor effect imaging performance.

2T Test Period	Rank	Rank	Rank	Rank	Rank
SOURCE	Q_{1hd}	Q_{2hd}	Q_{6hd}	Q_{5hd}	Q_{8hd}
R_1	1	2	3	3	
R_2	1	5	7	1	
PROCESS D	4	1	1	4	
R_1*R_2	5	5	4	7	
R_1*PROCESS D	5	5	1	6	
R_2*PROCESS D	5	2	4	2	
R_1*R_2*PROCESS D	1	2	4	5	
R^2	0.837	0.848	0.968	0.995	
Error (SS,DF,MSE)	(0.67,2,0.33)	(0.67,2,0.33)	(0.67,2,0.33)	(0.00,2,0.00)	
13T Test Period	Rank	Rank	Rank	Rank	Rank
SOURCE	Q_{1hd}	Q_{2hd}	Q_{6hd}	Q_{5hd}	Q_{8hd}
R_1	1	4	2	1	3
R_2	3	1	5	7	1
PROCESS D	2	2	2	5	3
R_1*R_2	7	4	2	2	3
R_1*PROCESS D	6	4	5	6	3
R_2*PROCESS D	5	2	2	4	3
R_1*R_2*PROCESS D	3	4	1	3	2
R^2	0.649	0.462	0.876	0.918	0.606
Error (SS,DF,MSE)	(4.17,9,0.46)	(3.17,9,0.35)	(1.5,9,0.17)	(0.03,9,0.003)	(1.67,9,0.19)

Table 4.9: Analysis of Designed Experiment (ANOVA) - Ph3340

Analysis of P3319, 3340 Blocked by Campaign: An analysis of this design with factors of R_2 type, Process D type, and run as the factor was completed at the $2T$ and $13T$ time periods. In the hot/dry conditions, we failed to reject the null hypothesis Ho, for most response factors. However, for the response variables Q_{1hd} and Q_{5hd}, a test for significant effects using the unweighted means model analysis of variance yielded a $P \leq .01$ as the threshold for rejecting the null hypothesis. I performed a stepwise general linear model analysis using all factors for each of the above quality indicators. The minimum tolerance for entry in the model =0.01, with a forward step-wise alpha-to-enter of (α) =0.15 and a alpha-to-remove of (α) =0.15.

For the quality indicator Q_{1hd}, the stepwise modeling generated a subset model with four predicators of quality: Run, R_2 type* Process D, R_2 type, and Process D*Run for a R^2 =0.703 and P<=0.06 or better for each factor. The Run had the strongest effect on Q_{1hd} performance with T= 25.795 and P =0.000. A similar analysis for the response variable Q_{5hd} exposed that the factors and interactions of R_2 lot, Run, and R_2*Process D effect performance.

The analysis of the separate full factorial designs for Ph3319 and 3340 indicated that the strongest factor effecting system performance was the R_1 type. The analysis of variance across these two runs also suggest that there are other sources of variability in the manufacturing system. However, with the R_1 HMB525, the overall production was more robust to changes in the R_2, process D, and other factors we could not control for directly in the experiment such as slight differences flow rates, oven temperatures, and mixtures of the other fluids in the system. The media produced across this blocked system using the HMB525 R_1 produced conformed to the product specifications at the 13T time period. The data listed in Table 4.3.3.2.0.7 is for HMB 525 R_1 averaged over the run so it includes both Type0 and Type1 Process Ds and R495 and R226 R_2 batches.

13*T* in Hot/Dry	Ph3319	Ph3340
	Mean ± 1σ	Mean ± 1σ
Limits	<=2.00	>=2.40
Q_{1hd}	1.00 ± 0.000	2.702 ± 0.057
Q_{2hd}	2.00 ± 0.086	2.606 ± 0.076

Table 4.10: Analysis of Ph3319 and Ph3340 Blocked by Production Run

Analysis of Ph3351 in Hot/Dry and Hot/Wet: The designed experiment for Ph3351 was analyzed in both Hot/Dry and Hot/Wet conditions. The experiment attempted to validate the run rule we derived from the CDT's to be able to successfully mix different batches of R_1 and R_2. In this experiment, the R_2 was held constant, and different batches of R_1 were tested. The four batches of R_1 were selected based on what was perceived, a priori, as their relative strengths in the imaging system. The group believed that performance in both environments were linked: that is, if the system performance was weak in hot/wet, it would also be weak in hot/dry. That is, a system that used a combination of R_1 and R_2 would be less likely to have hot/dry performance issues but might take longer to "age-in". The results of this experiment indicated the contrary.

The systems that performed poorly in hot and wet conditions, also had performance problems in hot and dry conditions. In the Hot/Dry conditions, the R_1 HMB was the major effect for the response variables Q_{1hd} and Q_{5hd} at the *2T*, *10T*, and *12T* test periods. The HMB 524 consistently outperformed all other R_1 types, regardless of the Process D type or Fluid A batch used. Of the HMB 12XX R_1, only the HMB 1209 could met the product specifications when run with the type 0 (standard process D) for that product prototype. In the Hot/Wet conditions, again, the R_1 type was the main factor in determining image performance. The HMB 524 R_1 consistently outperformed all other R_1 types used in that production run, providing better imaging results at all test periods.

There were two notable features of this experiment. First, the HMB524 R_1 consistently performed better in all environmental conditions. Second, the performance of the HMB 1207 and HMB 1209-2 R_1 for the response variable Q_{1hd}, degraded over time, dropping off sharply after the 9T test period. This behavior was also observed in the HMB 9XX R_1 from Ph3319 and Ph3340.

***Conclusions, Predictions, and Confirmatory Tests*:** We had a number of aims in running back-to-back production runs testing the same factors. The primary motivation was to maximize the amount of good material produced. Second, we wanted to confirm or reject the hypothesis that the primary effects of product performance were due to interactions between R_1 and R_2 types. The addition of Process D as a factor was necessary to evaluate the effects of different Process D methodologies on the product. Finally, two of these runs were blocked across campaign to learn more about the repeatability of the overall manufacturing system.

Only a limited number of combinations of materials could meet all the specifications and be released as conforming product. In these runs, the R_1 type had a significant effect on the performance of the run. The HMB9XX R_1 and most of the HMB12XX R_1 consistently exhibited in Hot/Dry conditions Q_{5hd} and Q_{1hd} values below specifications by the $13T$ time period or greater. The type of process D also effected the image performance of the run. In these runs, For R_1 HMB 9XX or greater, a Type-1 process D negatively effected the product by reducing image quality. This could have significant impact on plans to run this prototype in the Southern MA. facility which can only support a Type-1 Process D. The type of R_2 used in the system had only a minor effect of the performance of the product. However, the two batches of raw materials use to comprise the Type0 and Type1 R_2 tested in these combinations were considered similar rather than grossly different based on prior analytical testing.

On balance, these experiments highlighted to the Helios team that our attempts to manage the production of the current prototype using *"run rules"* would not be completely successful. While we were able to maximize the production of materials when using the HMB5XX R_2, the materials produced with the HMB 9XX R_1 or greater were usually unsuccessful and resulted in non-conforming product. Additionally, the performance of the product in extreme temperature conditions, hot/dry and hot/wet, for any R_1 prepared by the upstream supplier after May of 1993 was not linked. That is, certain combinations of raw materials and processing conditions exhibited performance problems in both hot/dry and hot/wet conditions.

Finally, a number of these individual designed experiments, when combined were blocked by campaign. That is, the combination of the HMB 525 R_1, R_2 types, and process D types were replicated in Ph3319 and 3340. At the 13*T* time period, media with this combination from either phase had satisfactory performance in the Hot/Dry environment. However, media from Ph3319 had on average better performance the quality indicators that signal hot/dry performance problems. The predominate factor affecting performance was the production campaign. It is important to note that these two runs were not perfectly replicated since the start-up and operation of the line as well as the fluid mix and coating processes are independent events. However, the production line appeared to be running within standard operating conditions during both production campaigns.

4.3.3.3. Improving Mechanistic Understanding the Product

One of my primary motivations for developing a historic data base and running the designed experiments listed above was to gain a better mechanistic understanding of the performance of the product. Good performance is dependent of the ability of the product to have stress-induced adhesive failure at the interface having the weakest link. While the experiments above improve our understanding of the system, they were focused on the system at a macroscopic level. That is, we worried about what batches of existing raw materials should we use to produce the media. We also want to gain more information on this system at a more fundamental level to be better able to select and or blend raw materials without having to perform extensive pre-production testing.

The physical strength of the one of the layers (which we will call **L** for the purpose of this analysis) may be an important indicator of system's performance. However, none of the current quality tests can measure this strength directly. For a given media prototype, L's strength may be a factor of the ratio of the primary raw material in L to the organic aqueous material (M) used to form the fluid needed to coat and dry the layer.

Experimental Design Strategy: The product designers recommend a L to M ratio of between 1:1 to 100:1. The current production ratio is somewhere within that range. The ratio of L to M cannot be measured by taking a sample of the blended material. Instead it must be calculated by knowing the percent solids of the "L raw material" received from the upstream supplier and the weights of the L and M added during the fluid blending processes. Over time, the group had noticed that the overall system performance had become "weaker" in the hot and wet conditions. This was confirmed by calculating the number of time periods it takes for the media to perform satisfactorily in all environments (*See Figures 4.1 and 4.2*). We hypothesized that the L to M ratio could be altered to adjust the strength of the layer and therefore the ability for the media to fail adhesively or cohesively as appropriate.

To confirm this theory, we ran an L4 orthogonal array (2 factors, 2 levels) with L batch as the first factor and L to M ratio as the second factor. All other raw materials, fluids, and process conditions were held constant. As with other experiments, we could not complete all runs in a single day. Therefore, production day becomes a factor we could not control for and also could not block.

Ph 3308-09	Factor A	Factor B	
Run #	L	L to M ratio	Day
1	L0	M0	1
2	L0	M1	1
3	L1	M0	2
4	L1	M1	2

Table 4.11: L strength matrix

Hot/Dry Performance -- The image performance of the run was measured for 7 to 10 quality attributes at the 1*T*, 2*T*, and 4*T* periods. There were only two quality measures Q_{5hd} and Q_{2hd} that showed strong response to these factors. The best performer in the 1*T* and 2*T* periods was the L1 layer material. When the L1 was run using the standard L to M ratio (M0), it consistently had good image uniformity and above average Q_{5hd}. The best Q_{5hd} was achieved with the L1 and a high L-to-M (M1) ratio while the best uniformity was achieved with the L1 and standard L-to-M ratio (M0). The performance of the L0 was improved for both image uniformity and Q_{2hd} by the use of a higher L-to-M (M1) ratio.

At the 4*T* test point, the performance of the media for image uniformity was the same as at the 1*T* or 2*T* test points. There was much less of a signal for Q_{5hd} at this time frame (that is, we failed to reject the Ho hypothesis -- Ho: $\mu_1=\mu_2$). At the nine week point, the Q_{5hd} signal reappeared with the L1 on average 10% higher than the L0.

Hot/Wet Performance: The motivation to adjust the L to M ratio was to be able to modify the strength of the L layer and change the behavior of the imaging system. There were three quality measures (Q_{2hw}, Q_{3hw}, and Q_{4hw}) that exhibited a response to these factors. These response variables were measured at the 2*T*, 4*T*, and 18*T* periods. Most of the effects were relatively weak, however, at the 4*T* and 18*T* periods, the interaction of

L*M was significant for the response variable Q_{3hw}. The combination of (L1,M0) had the expected performance outcome. However, the (L0,M1) combination was "stronger" than the (L0, M0) combination. The direction of the response variable Q_{4hw} was identical to that of Q_{3hw}. The values Q_{3hw} of are listed in the table below, where a value of 1 is "'weak" and a value of "10" is strong.

Hot/Wet		Q_{3hw}	Q_{3hw}	Q_{3hw}
L	L to M	$2T$	$4T$	$18T$
L0	M0	4	6	7
L0	M1	4.5	8	9
L1	M0	5	7	9.5
L1	M1	5	5	6

Table 4.12: Direction of Response Variable Q_{3hw} *as a Function of Time*

Conclusions, Predictions, and Confirmatory Tests: This experiment provided some insight into the factors influencing system performance. First, the increasing the L-to-M ratio should have "weakened" the system performance in both hot/wet and hot/dry conditions. We confirmed this result for the systems with the L1 material. However, for the systems with the L0 material we experienced the opposite outcome. Additionally, adjusting the L to M ratio for a given batch of L raw material can be used to "tune" system performance. While this might not be a practical method to use in a production environment, it reveals that the system may be sensitive to undesired changes in L-to-M ratio caused by measurement error or other factors during the fluid mix processes. To learn more about this possibility, the team should perform a set of tolerance runs, deliberately altering the L-to-M ratio once a final product prototype is developed.

4.4. Developing Accurate Classifiers

We have been focused earlier on the use of statistical modeling and Designed Experiments as a method for uncovering the mechanistic structure of a problem. Another aim for statistical modeling and particularly classification decision trees is to develop an accurate classifier. That is, we would like to be able to make a set of measurements before, during, and shortly after the time of coating and from those measurements predict which class the final product will be in. The use of CDT's or other traditional statistical modeling methods as a classifier may enable the Helios team to identify pro-actively which product at the time of coating is at risk of being a poor performer. If this analysis can be done while the run is in progress, it could help to provide timely feedback to the manufacturing group to assist in decision making. The team can chose to stop the manufacturing run, adjust or change the fluids, or change other processing conditions.

To gather the data needed for rapid decision making, it is advantageous to move to an automated system were the measurements are made in-situ rather than off-line in a test facility. A number of in-situ measurement systems are being installed in Norwood and will be included in the new coating facility in Southern MA. Since the coating process is continuous, a significant amount of product is processed during the time it takes to cut samples from the beginning or end of a coated roll and perform off-line evaluations. As much as possible, the team is trying to reduce the time it takes to make these measurements in order to minimize the loss of product. Excess numbers of pin-holes or other surface defects, low carbon black density or incorrect coating width can substantially reduce the final product yield even if the product images well all environmental conditions. Some of these physical defects effect the performance of the media in the imaging system. Our goal is to drive these types of physical defects to 0% as soon as possible.

We had found it difficult, however, to assess the long term imaging characteristics of the media from these types of physical quality or process measurements. To aide in that effort, a number of special imaging and peel tests are also performed the day of coating. Prior to testing, the media is specially treated to "accelerate" aging of the media. The accelerated media is imaged using a Helios printer and the evaluation group rates the media for the standard image quality attributes (Q_1, Q_2,...Q_n). In addition, the specially treated media is also imaged and peeled to determine the adhesive and cohesive strength of a number of the key layers. Ideally, this data can be used to predict final image performance or the performance of the media at some future point in time (as it ages in).

Because of the difficulties the group had in organizing the in-process test data and comparing it to final performance, much of the in-process image and peel data was not actively used to gauge the quality of the coating run. The "accelerated" performance data could be a rich source of information about the on-going production run. To be better able to use this data for decision making, I organized the accelerated image and peel information and placed it in the relational database. The backbone of the database is the game plan or run plan for each day or set of production days. Each set of accelerated image and peel data is associated with a "case". We found it highly desirable to perform both the accelerated imaging and peel testing on samples taken from the same phase and roll. As with the more typical "aged-in" performance data, we were able to load into the database a reasonable number of cases (>80 cases) which could be extracted from the production and test runs over the past twelve months.

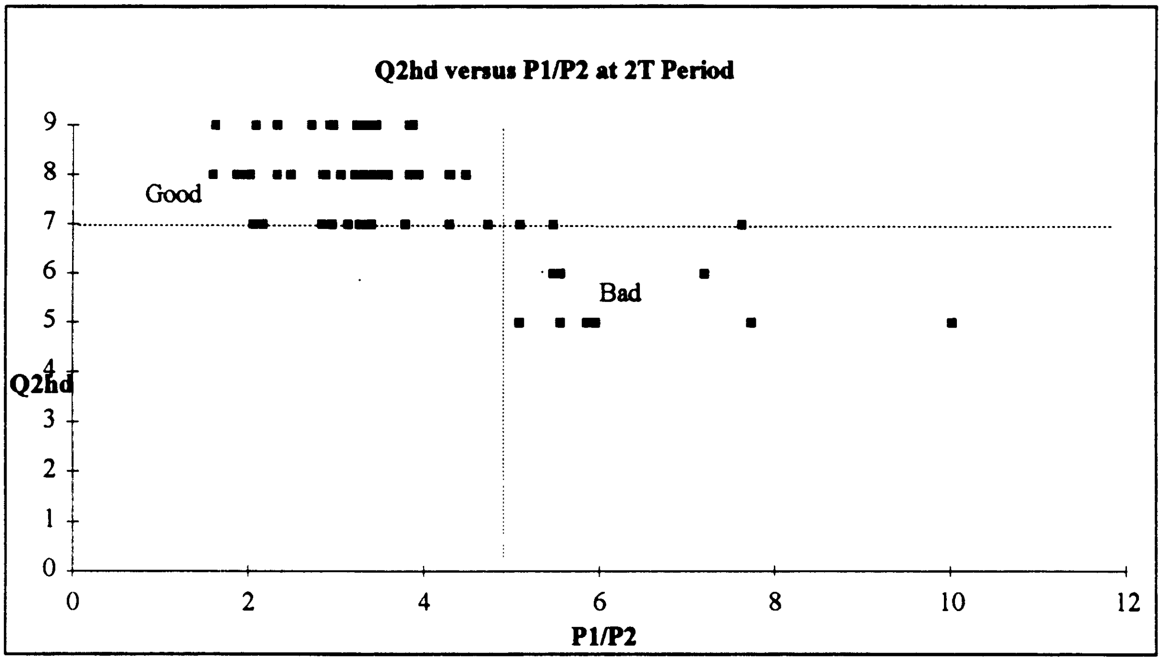
There is a healthy skepticism among the Helios team toward accelerated aging tests. A usual concern is just how valid is the acceleration method. This is based on the significant past experience Polaroid has with accelerating testing methods in the silver halide film world. In the Helios world, the use of accelerating testing is relatively new. In these tests, very fresh and unfinished media is put into a separate process D and other off-line process steps. The parent roll that the test sample is taken from continues to undergo a number of additional processing steps before it is formatted or stored.

The general aim of the accelerated testing methods currently in place was to create a test that approximates the performance of the media when it is completely aged in. However, if the media in general ages variably, a question arises as to just what point in time the "standard" accelerated testing simulates. In addition, since the media is exposed to alternate processing, does the resulting imaging and peel performance mimic performance in room temperature, hot/dry, or hot/wet conditions.

To answer these questions, we attempted to correlate the existing accelerated image and peel data to image performance in the hot and dry environmental conditions at the $2T$ periods. This test period was chosen because we had the most complete performance data base on testing done at that time interval. The hot/dry conditions were selected since poor performance in this environment renders the media non-conforming. There were three main measurement variables from the peel data that were used to develop a relationship: P_1, P_2, and P_2m. These variables were chosen because of the results two sample t-test (continuous variables) or from chi-square tests for independence (dichotomous variables). In an attempt to reduce the number of variables, I also used a ratio of the peel strengths of P_2/P_1 and P_2/P_1^2. The first of these ratio's was selected because it has meaning related to the mechanical performance of the media in the system.

To analyze the data, plots of the major quality indicators of imaging in hot/dry conditions were plotted versus each of the five peel performance variables listed above. Since most of the image quality indicators are subjective measurements, the plots as well as more traditional correlation statistics were used to determine which peel measurements highlighted changes in image performance. For this analysis, a trend emerge. For materials produced in Ph3153 through Ph3218, the ratio of $P_{2/}P_1$ or $P_{2/}P_1^2$ was a good predicator of product performance at the 2*T* interval. A simple correlation of image performance Q_{2hd} to $P_{2/}P_1^2$ yielded a correlation coefficient **r** = 0.70. A similar correlation was obtained for $P_{2/}P_1$ and the two measures are highly correlated to each other (r=0.95). The plot of the ratio versus Q_{2hd} in *Figure 4.3.* below, shows there are rectangles of good performance when the $P_{2/}P_1^2 <= 1$. There appeared to be little relationship between image performance and P_1 at this time interval. The overall image performance of the product in this group stayed relatively constant when re-measured at subsequent time periods.

We had tried to use these indicators to gauge the progress of subsequent production runs, especially those described in the experiments in Section *4.3* above. The first test was for Ph3243-46 and the results were similar to the runs listed above. However, a major shift in performance was observed starting with Ph3284 through 3340. The overall ratio $P_{2/}P_1^2$ shifted upward with most of the cases in these runs experiencing a ratio $P_{2/}P_1^2 > 1$. The reason for the shift was not clear, however, on average, it was driven by a reduction in the value of P_1 rather than an increase in P_2. While the performance of most of the cases in this block of production runs was satisfactory at the 2*T* period, a portion of the material suffered a degradation in performance by the 10*T* period and could not be released as conforming product. When the cases for the all runs between Ph3154 to Ph3340 are combined in the analysis at the 2*T* period, the correlation of this indicators to Q_{2hd} was reduced to r<=0.40.



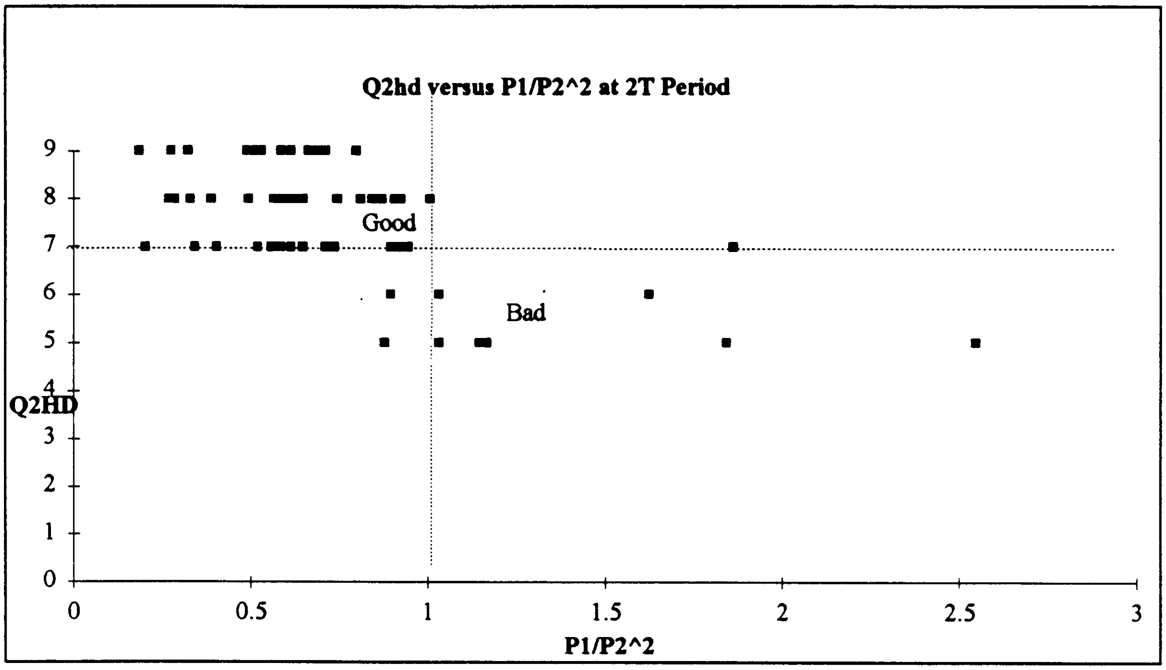


Figure 4.3: Correlation of Accelerated Peel to Image Performance in Hot/Dry

It would be useful to take this analysis further and repeat the exercise using 10*T* or 15*T* period test data. Unfortunately, most of this data is not available for the earlier production campaigns. At this time, the group can not make production decisions based on the outcome of the accelerated peel tests. Therefore, it may be prudent to discontinued these tests until production is shifted to the new media prototype or into the new production facility. The analysis did however, reveal a major shift in the ratios P_2/P_1 or P_2/P_1^2 might be signaling a new interactive effect between the various layers of the system.

4.5. Summary of Process Analysis and Experimentation

The team had initially hoped that by organizing and analyzing the historic operating data, and running designed experiments, we would uncover "levers" to be able to control the production of the current media prototype. The analysis indicated that while a "few" process and raw material levers exist, we still lacked fundamental knowledge about what attributes of the various raw materials and fluid layers in the media affected systems performance. Therefore, it would be difficult to plan and control large scale production runs in the southern, MA facility using the current media prototype. This provided the team with sufficient motivation to help speed along the development of a new, robust media design.

What we did learn about the overall manufacturing system was helpful in developing and implementing a manufacturing release system that ensures only conforming media is released to the customer. We were able to influence and redesign, were necessary, the type of testing and feedback required to assure the quality of the imaging system.

5. Enhancing Organizational Learning and Systems Performance

The aim of the our manufacturing release system is two-fold. The primary mission is to assure that the product that is released to finished good's inventory will meet the customer's expectations. The second mission is to use operating data and customer feedback to continue to improve the manufacturing system. The manufacturing system is more than a set of production processes. It involves all aspects of production including people management, decision making, process improvements and product improvements. The information captured in the manufacturing release process is a key asset of the manufacturing and development organizations. The organization that can learn more rapidly from its experiences and use that learning to enhance its performance will have a competitive advantage in the marketplace.

5.1. Implementing a Data Driven Approach to the Manufacturing Release Process

The goal of the Helios medical media Manufacturing Release System is to ensure that all Norwood 2 Helios Medical media products are manufactured in accordance with FDA requirements of Good Manufacturing Practices and consistently conform to specified customer requirements. The Norwood organization is also currently pursuing ISO9000 Certification. Polaroid's TQO principles are the guiding force behind the manufacturing release system as well as the design and operation of the ISO9001 Quality System.

The customer's performance expectation of Helios film media is not based solely on the manufacturing quality of the media but on the performance of the media in a Helios Imager. Therefore, we developed an internal Manufacturing Release program for Helios Medical products that includes a number of quality tests to verify the performance of the Helios media in the imaging system.

The Helios team believes that quality should be the responsibility of every Polaroid employee owner directly or indirectly involved in the manufacturing of Helios medical media. Therefore, an organizational structure and responsibilities have been developed to support this goal. The Norwood technical Evaluation Manager directs the manufacturing release effort. This individual does not have direct responsibility for the performance of the Helios film media manufacturing operation. The Manufacturing release system incorporates the following functions to ensure compliance with the FDA GMP:

1. Review of production records;
2. Approval or rejection of all manufacturing materials, components, in-process materials, packaging materials, labeling, and finished devices; approval or rejection of devices manufactured, processed, or packaged, or held under contract by another company;
3. Identifying, recommending, or providing solutions for manufacturing release problems and verifying the implementation of such solutions; and
4. Assuring that all manufacturing release checks are appropriate and adequate for their purpose and are performed correctly.

5.1.1. Review of Production Records

The production process is carried out under controlled conditions and all operations that directly affect the product qualities are identified. A weekly Product Release Meeting, a daily Manufacturing Run Meeting (during all production runs), and a weekly Finishing/Packaging meeting are convened to review the production and quality records from the following process areas;

- Media Fluids/Chemical Mix
- Media Web Conversion/Coating Operation

- Media Finishing/Formatting Operation
- Media Sorting/Quality Control Operation
- Media Packaging Operation
- Media Shipping Operation

The intent of these meetings is to review the Helios 8x10 Medical Media Production operations and identify any issues that may negatively impact the quality and conformance of the product. The Evaluation Manager, manufacturing engineers and Product Manger ensure that the appropriate corrective action is implemented.

The production team has put in place written procedures which describe the methods and responsibilities for manufacturing, testing, and inspecting the media in-process and the final product to ensure that the manufacturing process is capable of producing product that conforms to specific requirements and customer needs. The Manufacturing engineer in each production area has ongoing responsibility for reviewing the inspection and test status of the product in-process. Any production lots that are determined to be non-conforming at any step of the production process are documented and identified for disposition.

Our goal is to move to a production system such that only product that is conforming is release from each stage of the production process for subsequent processing. Non conforming product should be scrapped since rework is possible only on a limited basis and is quite expensive. The manufacturing processes and quality test procedures are described in the reference documents listed in this section.

The results of the quality testing and inspections from each Production operation in the Helios Media manufacturing process are reviewed at the weekly Helios Medical Media

Release Meeting. The meeting is attended by representatives of the Production Operations, the product testing areas (Technical Evaluation Laboratory and In-Process Laboratory) and the Evaluation Manager. When the finished product is designated as non-conforming, a disposition is made by the team to whether the product lot should be scrapped, reworked, released, or re-graded for use in other Polaroid internal operations were appropriate.

If rework is possible, the finished product is re-inspected by the quality engineer and or manufacturing engineer to determine the disposition of the lot. If non conforming product is released, it will be marked as non conforming and reported as such to the purchaser..

Norwood Reference Documents: There are a number of reference documents including a Quality System Policy manual, procedures, work instructions, production specifications, and testing procedures that have been compiled by the Helios team to facilitate this effort. The formal documentation includes:

- Production Operations and Inspections
- Quality Testing Specifications
- Production Specifications

5.1.2. Developing Approval or Rejection Criteria for Components and Materials

The Helios Medical 8x10 Media Production operation ensures that all components, manufacturing materials, in-process materials, packaging materials, labeling, and finished devices; as well as like materials produced under contract by another company meet customer specifications. A set of material and component specifications shall be developed for the following general production material inputs:

- Chemical raw materials
- Base Stock for Web Conversion
- Base Stock for Thermal overcoat material
- Thermal overcoat
- Packaging Materials

Suppliers, both internal and external, are selected based on their ability to supply materials, products, and services that meet or exceed the specifications of the High Resolution Media Manufacturing and Development operation. In addition, partnerships are or shall be developed with suppliers to enhance the development of products and processes and provide for continuos improvement of the Media operation.

The Manufacturing or materials engineers in each of the above material areas have developed a quality control system to evaluate whether incoming materials meet the product specifications and should be accepted for use in the production or packaging of High Resolution media. Incoming materials that are designated as non conforming may be re inspected or re tested at the request of the manufacturing engineer or product manager. All questionable materials are placed in a hold status by the appropriate manufacturing or materials engineer the inspection is complete.

The materials or manufacturing engineer, Evaluation Manager, and other team members review the inspection data to determine the disposition of the questionable materials lot. The end-users of these materials and components shall work with the Quality system process owner to continuously review the specifications and the functional testing methods.

There are up to three levels of acceptance testing required for materials or components used in High Resolution Media production:

1. Vendor testing to ensure all materials shipped to Norwood meet established specifications
2. On-site analytical testing at Norwood and or other lab analysis
3. Out-of-order introduction testing

The kind of testing is specified in the Acceptance Documentation sheets which is initiated for each lot or materials or components received. The Materials inventory status report of all approved and non-approved materials is maintained electronically and distributed to the operations manager and technical and product managers.

A weekly Raw Materials Meeting and a weekly Manufacturing Release Meeting shall be convened to review the acceptance testing of chemicals, base and thermal stock and packaging materials. The intent of these meetings is to ensure that raw materials and components which conform to the production specifications are used in the production or packaging of Helios Media. These teams identify any issues that may negatively impact the quality and conformance of the product. Non-conforming materials will be rejected or regarded for use in other operations were appropriate.

Our analysis of the historic operating data and designed experiments alerted the team to potential raw material issues and interactions. In response, the product management team and evaluation manager, as well as the chemical operations group, became more involved in raw materials introduction and selection. As a team, we created three categorizes for raw materials taking into account the potential impact that material has on imaging performance. Materials arrive either "fit for use", or are placed in a "low risk" or "high risk" category. Based on that categorization, the team manages the introduction those materials to the manufacturing system.

Norwood Reference Documents: There are a number of reference documents including work orders, production specifications, and testing procedures that have been compiled by the Helios team to facilitate this effort.

5.1.3. Identifying, Recommending, and Providing Solutions for Manufacturing Release Problems

The High Resolution Media Production operation actively solicits feedback on the performance of released media from both external and internal customers. The main sources of Helios media and systems performance are:

- Twice weekly Beta Site and sales reference account meeting
- Weekly Technical Field Service meeting
- Weekly Media/Hardware Reliability meeting
- Weekly Hardware Burn-in/System Verification meeting
- Field Service Call Database

These meetings are convened regularly and attended by cross-functional team members from Media production and technical support, Hardware production, Product Marketing, and Technical Field Services. The intent of these meetings are to review the performance of released imagers and media run in combination in the field. The teams identifies hardware, media and systems interaction issues that may affect the reliability, quality, and performance of the Helios imaging system at the customer site. We produce a root cause analysis of identified problems and implement the appropriate corrective actions in hardware or media production.

The customer input obtained at these meetings are also a source of feedback regarding the applicability of the performance specifications for media production and quality testing and inspection methods. The Evaluation Manager works with the Manufacturing engineers and process engineers to identify which quality testing methods/functional tests must be added or modified to ensure the quality of the product. The Evaluation Manager is also notified of all Engineering Corrective Actions and changes in quality testing to ensure that the product continues to meet the company and customer requirements.

5.1.3.1. System Verification

A major source of feedback and information about the performance of the Helios system is through the System Verification Process. Polaroid was just starting up a Verification process when I joined the group in June. We had a number of objectives for verification that were defined by inside customers -- mainly Film Manufacturing, Hardware Manufacturing, and Systems Reliability. The primary objectives of the system are as follows:

- Provide an ongoing signal of imaging and system reliability of the latest combinations of media and printers;
- Formally verify release decisions for film and other film components;
- Establish a long term system performance database; and
- Strengthen the partnership between the film and printer manufacturing groups.

These objectives are complimentary to two of the main functions of the manufacturing release system (function 3 -- identifying, recommending, or providing solutions for manufacturing release problems and verifying the implementation of such solutions; and function 4 -- assuring that all manufacturing release checks are appropriate and adequate for their purpose and are performed correctly).

System verification is carried out in a controlled setting. From each media production run, an amount of material that has been determined to conform to all production specification is released to the an internal customer - the High Resolution Hardware Manufacturing group. This media, as well as media previously released to finished goods inventory and purchased from the Polaroid distribution center, is used in the hardware manufacturing process to burn-in or cycle the imagers. A set number of standard images are produced during the burn-in-cycle and the rest of the cycles are used to evaluate hardware reliability, media handling, and or hardware/media interactions. The standard images are evaluated against the media performance specification in addition to being used to verify the performance of the media is a integral component in the Helios 8x10 Medical Laser Imager imaging system.

We reviewed the results of this the verification tests weekly as a cross functional team with representatives from media manufacturing, product engineering, and hardware manufacturing. The team identifies issues that may negatively impact the quality and conformance of the Helios Imaging system and appropriate corrective actions are implemented. During the course of my involvement on the team, we had the opportunity to run over 50,000 cycles with media from more than six production campaigns and many printers. From that effort there are a number of deliverables:

- A regular report to the System Verification customers that provided information on:
  - Image performance;
  - Hardware Reliability; and
  - Continuous improvement efforts.

- The identification and correction of a number of Hardware/Media interactions; and

- The development and implementation of root cause analysis and corrective action procedures to react to any "signal" from the hardware, media, or hardware/media combinations during verification or burn-in testing.

Image performance of the system is evaluated for the 7 to 10 major quality parameters and compared to the quality testing results completed in Norwood. For example, for the quality parameter Q_{3rt}, the results of the image evaluation for 7 verification cells (a cell usually contains media from a single manufacturing campaign and a single version of hardware and ranges from 1750 to 6700 imaging cycles), are shown in Figure 5.1. below. The verification cells are constructed so that a given amount of media from each production day is used in at least five production imagers.

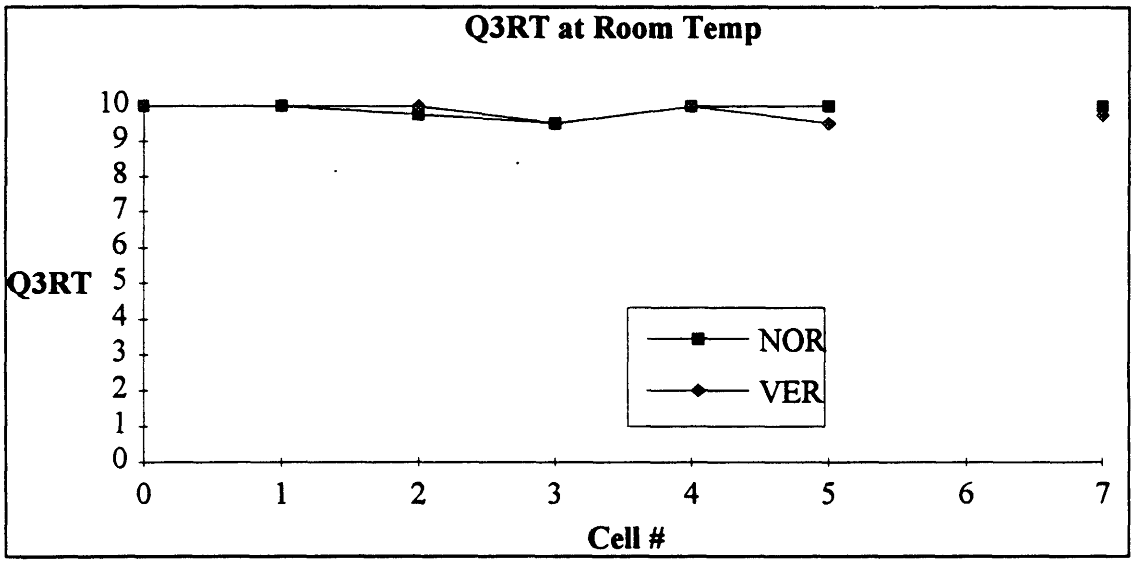


Figure 5.1: System Verification -- Cells 0 to 7 for Q_{3rt}

We also performed a two factor ANOVA with the production run and imager as the factors to learn more about the sources of variability within the Helios system. The ANOVA analysis represented media and imagers through System Verification in cells 0 through 4. Most of the cells were well balanced so that each imager ran media from at least different two production days and media from each production day was run on at least four imagers. Because the underlying probability distribution of the response variables did not appear to be normally distributed, reliance on a strict interpretation of the ANOVA results was misleading.

I have summarized the results of the ANOVA analysis in Table 5.1. below. There should be some caution in interpreting these results. First, only factors with a P value of P<=0.01 was interpreted as significant (each cell had a different number of runs, so the F ratio for varied). Second, the target image used to evaluate image performance is not designed to test for "systems verification or systems interactions". Finally, we use the image performance results mainly to verify the teams decision to release the media to the field. In all cases, the image performance results obtained in verification testing was similar to that achieved using a single imager in Norwood. While we observed some variability in performance within a single quality measurement, there was no signal that would indicate that the decision to release media to the field be questioned. Therefore, the information we obtained from the ANOVA or non-parametric T testing should be used to further our efforts to develop a Systems verification target image.

ANOVA	Q_1	Q_2	Q_3	Q_4	Q_5	Q_6
Cell 0	Phase	Phase	n/a	n/a	Both	n/a
Cell 1	Imgr	Both	n/a	n/a	n/a	n/a
Cell 2	n/a	n/a	n/a	n/a	Both	n/a
Cell 3	n/a	n/a	n/a	Imgr	Both	n/a
Cell 4	n/a	Both	n/a	Imgr	Both	Imgr

Table 5.1: Analysis of Variance for Systems Verification Runs (Cells 0 to 4)

We also track both hard and soft machine failures for each imager through the verification process. These results were combined and reported at the cell level (usually 10 or more imagers with 5000 or more cycles) and then aggregated for the reporting period. The group completes a Pareto Analysis separately for the Soft failures (failures than can be cleared by the operator) and hard failures (failure which result in a service call). These results are compared to both the Polaroid reliability targets and used to benchmark the corporation against outside competitors. The results of this Pareto analysis are used internally in the corporation to help improve systems reliability.

The System Verification testing was carried out with mostly non-incremental resources. The hardware manufacturing organization had already implemented a burn-in tests as part of their hardware qualification process. The time and effort we spent as a team analyzing the results and performing root cause defect analysis did enhance our learning effort and strengthen the partnership between the two manufacturing organizations. We also modified in-house testing of media based on the results generated from verification testing. System Verification also provides the group with controlled reliability testing which can be used as a point of comparison with the results the customer's are achieving in the field.

5.1.4. Ensuring Manufacturing Release Checks are Appropriate and Adequate

The manufacturing release system described above was implemented over the course of the internship process. The Helios team continues to improve this system as they gain more experience with the product and the manufacturing processes. An important step in the PDCA process is also to verify or audit that all the steps are in place and followed. A series of internal and eventually external audits are or have been carried out with that intent.

The purpose of a quality audit is to verify whether the quality activities comply with planned arrangement as well as determine the effectiveness of the quality system. Audits will be planned and conducted on a regular basis. The results will be documented and reviewed by appropriate personnel in a timely manner and serve as a basis for timely corrective action. The assigned audit team is responsible for initiating a corrective action request for each deficiency found the Internal Quality Audit and forward the request to the Quality System Group Manager and the Technical Manager. The Quality Systems Group manager will be responsible for overall coordination of internal audits. The responsibilities and procedures for internal quality audits is documented and published.

5.2. Translate Knowledge to a New Product or Prototype

The mission of the N2 manufacturing system (people, technology, capability), is to develop new imaging media in the shortest possible time-frame. To achieve those results, N2 must work cooperatively with product design, hardware reliability engineering and other groups responsible for helping to produce the Helios Systems. The N2 organization attempts to provide robust process technology, expertise and knowledge for the scale-up from low volume manufacturing to high volume manufacturing at the new facility in southern, MA.

A major focus of the efforts at N2 is to improve the corporations' time to market for each subsequent high resolution imaging product. Additionally, another objective should be to improve the reliability and availability of each new Helios system or version introduced. To achieve these objectives, the team must be able to learn from each production or test run complete in the N2 facility or other test coaters. This requires the use of accurate data, management information systems, and data analysis tools to maximize learning and knowledge transfer from each phase of the product life cycle. Much of this information can be captured in the manufacturing release process.

5.2.1. Motivations for a New Media Prototype

As a team, we had made significant strides in managing the manufacturing system and product release system for the existing media prototype. At the start of production of this media prototype, product yield (or imaging yield) was substantially under target. Now, product yields had increased to a point were we were able to release media from a substantial number of production runs. However, there were still opportunities to improve the manufacturing system and the product performance. These improvement opportunities fall into two major categories:

- Imaging Systems Performance
  - Consistent image performance in all environments
  - Consistent peel performance in all environments
  - Increased imaging range
  - Improved uniformity of the image

- Manufacturing Systems Performance
  - Reduction of aging variability
  - Increased imaging yield
  - Improved coat-ability
  - Enhanced robustness to raw material and fluid variability

These performance enhancements should not only increase customer satisfaction with the Helios system but also improve manufacturing robustness and reduce costs. There are significant opportunities to reduce the cost of manufacturing. The current approach that the team was using to manage each production run actually increases that amount of raw materials inventory needed on hand. It also requires a change to the raw material introduction process or testing process. At this point in time, the increase in raw materials and holding costs is offset by the increase in imaging yield. However, if we could gain both high imaging yield and increased tolerances to raw materials variations this would be the best of both worlds. In addition, if we could reduce or eliminate the aging in period, the product would be easier to manage, inspect, and qualify for release to final goods inventory.

5.2.2. Accelerating the Development Effort

The development of a new media prototype is underway and should be completed before this thesis is published. There were a number of lessons we took forward from our work with the original production prototype which helped complete the development effort and speed the introduction of a new prototype to the field. These included:

- The establishment of a common set of goals for the new prototype (including both imaging performance as well as manufacturing performance);

- The use of structured problem analysis methods such as the Kepner-Tregoe methodology or other TQO tools to assist in problem identification and structured problem solving;

- The implementation of a relational database and database design to capture information on all aspects of the manufacturing system related to the new product design -- including formulations, raw materials used, fluid mix processes, coating processes, quality testing, and customer feedback were applicable. For each "case", we strive to have a complete measurement set;

The use of statistical analysis and modeling tools such as univariate and multivariate diagnostics and CDT's to uncover the cause-and -effect relationships and common factors;

- Running Designed Experiments rather than one-factor-at-a-time testing to maximize learning and improve process robustness; and

- Initiate tolerance testing to ensure that the new prototype is robust to minor variations or changes in both raw materials, fluid mix, and coating processes.

We accomplished the above by the committed participation and contribution of all team members. Our attempts to learn from our production experience with the existing media prototype helped to structure our approach to the development of the new media prototype. By focusing on both image and manufacturing performance objectives, early testing on the new prototype indicates it will improve customer satisfaction with the Helios system and help reduce the cost of manufacturing the product.

6. General Observations and Recommendations

6.1. Observations and Conclusions

During the past six to nine months, Polaroid has made dramatic progress in establishing, managing, and improving the Manufacturing Release Process. The Helios media organization has recognized the value of accurate information and the need to manage the manufacturing systems by fact. The result has been the establishment and or improvement of the product test and management information systems which provide the feedback on product performance necessary to reduce the time-to-market for new products as well as enhance customer satisfaction with existing products.

The central themes which unites our effort in establishing a customer driven Manufacturing Release process include:

- Recognizing the value of collecting, organizing and analyzing historic operating data.
- Employing statistical modeling tools to help identify cause-and-effect relationships to link quality data to operating information. The focus of this effort should be on developing easy to follow "run rules" rather than complex mathematical models.
- Using designed experiments to validating a solution or region of the decision space; enhancing mechanistic understanding; reduce process variability, and refining or re-engineering the product.
- Incorporating our learning into the manufacturing release process to ensure that we continually meet the customer requirements.

- Communicating the results of this effort to all team members to ensure better technical and management decision making.

The process of collecting, analyzing, and using the process and quality data to enhance decision making was in itself an iterative learning process. Each attempt we made at analyzing and organizing the data taught us something about the manufacturing system which we could incorporate into the new management systems or process models.
We also had the opportunity to experiment with different database systems, statistical analysis packages, and modeling methodologies and select the best "systems" for use in the production environment.

When I first arrived in Norwood, I perceived that Polaroid did not have a "strong" tradition for structured and formal communication. I believe, as a I learned more about Polaroid's corporate culture through the internship process, I helped provide some structure to the efforts of problem identification, analysis, and problem solving which were accepted and will be beneficial to the group in the future.

I also feel that, as a team, the Norwood organization strengthened its relationships with product development, design, and hardware engineering over the course of this learning process. Our work with hardware manufacturing and reliability through the System Verification testing, as well as other ongoing attempts, enabled the group to produce a more robust imaging system. In most instances, we documented and communicated these results so that other groups within the High Resolution Imaging organization can learn from our efforts.

6.2. Recommendation of Areas for Future Consideration

Norwood would like to move to a manufacturing system were media is coated, formatted, and packaged without concerns about product aging. The development of a new media prototype which meets this objective and provides improved customer performance is nearly complete. However, the work with the product development and other groups should not stop there. We uncovered a number of areas for further study during our structured problem solving exercises and placed in the "parking lot" lists. These included:

- Increasing our efforts to characterize and analyze raw materials;
- Development of an on-line database (accessible to all team members) to improve raw material tracking and fluid mix processes;
- Modeling of the mechanical function of various layers in the media structure;
- Improving mechanical/peel testing methods; and
- Developing in-situ tests of image performance to enhance opportunities for process feedback and correction.

The more the team understands about the sources of variability in the coating processes, fluids mix processes, and raw materials, the closer the organization can move to a true customer driven environment. The ultimate vision for this product should be a supply chain capable of delivering inventory to the user with the barest amounts of inventory at each stage. For Norwood, this would mean a significant reduction in the amount of raw materials on hand and also a reduction in raw material (out of order introduction) testing.

Implementation of this type of manufacturing system would be to free up time on the production coater in Norwood for development of future High Resolution Imaging products rather than pre-production testing for current media prototypes.

The goal of this thesis was to address the critical issue of using historic production information to assure quality, as well as provide a basis for continuous improvement and learning. The final measure of its success will be if it stimulates the reader to think of future opportunities to apply this work to practical business situations within Polaroid or other settings.

Appendix 1: References

1. Anderson, Larry H., "*Controlling Process Variation is Key to Manufacturing Success*," Quality Progress, August 1990: 91-93.

2. Breiman, L., et. al., Classification and Regression Trees. CA: Wadsworth Publishing, 1984.

3. Cargill, E.B. and F. Habbal, "*Quality Characteristics of the Polaroid Helios Laser System*", White Paper: Image Quality. Newton, MA: Polaroid Medical Imaging Systems - Marketing Publication, 1992.

4. Cargill, E.B., et. al., "*A report on Polaroid's New Dry Imaging System for Generating 8x10 Radiographic Films*", White Paper: Technology. Newton, MA: Polaroid Medical Imaging Systems - Marketing Publication, 1992.

5. Corey, E. Raymond, ed. MBA Field Studies: A Guide for Students and Faculty. Boston, MA: Harvard Business School Publishing Division, 1990.

6. Dertouzos, Michael L., Lester, Richard K., and Solow, Robert M., Made in America. Cambridge, MA.: The MIT Press, 1989.

7. Dillon, William R. and Matthew Goldstein, Multivariate Analysis: Methods and Applications, New York, NY: John Wiley & Sons, 1984.

8. Food and Drug Administration, Good Manufacturing Practices: Code of Federal Regulations, CFR 21 - Part 820a & 820b.

9. Heim, Joseph A., and W. Dale Compton, Editors, Manufacturing Systems: Foundations of World-Class Practice. Washington, DC: National Academy Press, 1992.

10. Hetzel, William B., Cycle Time Reduction and Strategic Inventory Placement Across a Multistage Process. Cambridge, MA: MIT Master's Thesis, Leaders for Manufacturing Program, 1993.

11. Hogg, Robert V. and Johannes Ledolter, Engineering Statistics. New York, NY: Macmillan Publishing Company, 1987.

12. International Organization for Standardization, ISO 9001: Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing. Switzerland: ISO Technical Committee, Reference ISO 9001:1987 (E).

13. Kepner® Tregoe, Kepner® Tregoe Executive Problem Analysis and Decision Making. Princeton, NJ, 1973.

14. Kiemele, Mark J. and Schmidt, S. R., Basic Statistics: Tools for Continuous Improvement, Colorado Springs, CO: Air Academy Press, 1990.

15. *"Laser Imaging Systems"*, Second Source Imaging: The Medical Imaging Equipment Magazine, July 1993

16. Little, John D. C. *"Are There "Laws" of Manufacturing?"*, Manufacturing Systems: Foundations of World-Class Practice. Joseph A. Heim and W. Dale Compton, Editors. Washington, DC: National Academy Press, 1992.

17. *"Managing for Quality"*, Business Week, Special Issue 1991: 33-61.

18. McWilliams, Gary. *"A Radical Shift in Focus for Polaroid"*, Business Week, 26 July 1993

19. Mock, Theresa Lai-Hing. Reducing Process Variability in Chemical Batch Manufacturing. Cambridge, MA: MIT Master's Thesis, Leaders for Manufacturing Program, 1992.

20. Nahimas, Steven. Production and Operations Analysis. Homewood, IL: Richard D. Irwin, Inc., 1989.

21. Saraiva, Pedro M. Data-Driven Learning Frameworks for Continuous Process Analysis and Improvement. Cambridge, MA: MIT Ph.D. Thesis, 1993.

22. Saraiva, Pedro, and George Stepanopoulos, *"Continuous Process Improvement Through Inductive and Analogical Learning,"* AICHE Journal, **38**(2), 161 (1992).

23. Senge, Peter M. The Fifth Discipline: The Art and Practice of the Learning Organization. New York, NY: Doubleday/Currency, 1990.

24. Schmidt, Stephen, and Launsby, Robert G., Understanding Industrial Designed Experiments. 3rd Edition, Colorado Springs, CO: Air Academy Press, 1991.

25. Schein, Edgar H. *"How Can Organizations Learn Faster? The Challenge of Entering the Green Room"*, Sloan Management Review, Cambridge, MA: Winter 1993

26. Shiba, Shoji, Alan Graham, and Walden, David. A New American TQM: Four Practical Revolutions in Management. Cambridge, MA: Productivity Press, 1993.

27. Sonquist, J., et. al. Searching for Structure. MI: University of Michigan, 1971.

28. Stephanopoulos, George. Chemical Process Control: An Introduction to Theory a Practice. Englewood Cliffs, NJ: Prentice-Hall Inc., 1984.

29. Taguchi, G., Introduction to Quality Engineering. Asian Productivity Organization, 1986.

30. Womack, James P., Jones, Daniel T., and Roos, Daniel. The Machine that Changed the World. New York, NY: Rawson Associates, 1990.