Total Quality
Process Control for
Injection Molding
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Total quality process control (TQPC) for injection molding is the process for the repeatable manufacture of a product that consistently meets the customer’s requirements. Senior management is responsible for providing the assets, direction, and support to ensure TQPC is implemented, maintained, and practiced daily throughout all company business and manufacturing operations.

Quality begins with senior management implementing a policy for excellence and an attitude that it is achievable. An example of a successful company’s quality policy is as follows:

We, as employees of “COMPANY,” are dedicated to the delivery of quality product and technical services contributing to the success of our customers throughout the world. We believe high ethical standards are essential to achievement of our individual and organizational goals.

How a company achieves this or its own specific quality policy and goals is through the use of proven quality management, operations, and methods (e.g., ISO 9001:2008, Total Quality Management, Six Sigma) and other proven quality methods. Process control, with statistical process control (SPC), is just one section of this national standard that requires the company to develop quality methodology to ensure a quality operation is built to provide continuous quality product and services to its customers in a repeatable process. Quality is not the standard; it is the only standard for successful business operations.

This book focuses all the personnel and resources of a company toward a plan to implement total quality process control procedures for the production of plastic parts.
The focus is on management’s desire and direction to implement the program by providing the assets, guidance, and information to manufacture plastic parts “right the first time.”

The quality process begins with sales and continues through the company’s different departments, be they large or small, including finance, purchasing, design, tooling, manufacturing, assembly, decorating, and shipping. All personnel have a responsibility and effect on the success of their total quality process control program.

The book explores in detail the methods and procedures that have obtained solid positive results in satisfying their customers’ quality part requirements. These techniques have reduced cost, improved product performance, and increased customer satisfaction and profitability for both themselves and their customers.

Each chapter explores in detail different ways to improve part design, processability, and total manufacturing and part quality. Also included are material and process control procedures with control charting in real time to monitor quality through the entire manufacturing system. By adherence to these methods, the tooling for part production and the manufacturing equipment will always be capable of producing product to meet the customer’s quality requirements.

Problem analysis techniques and troubleshooting procedures are also presented to improve a company’s process control system and solve manufacturing problems with a minimum of time and expense to maintain production schedules and delivery requirements.

Any company, large or small, cannot afford not to adapt all or at least a major portion of the total quality process control procedures to be discussed. Competition is always knocking on our customers’ doors, and the only way to counter their threat is to provide a high-quality product within a realistic time schedule and at a fair market price.

ACKNOWLEDGMENTS

I want to extend my appreciation for the love and support I received from my family and especially my wife Joyce during the years of writing this technical book. I also want to thank Dean Wakefield, Carolina Jacobson, Ron Smith of Cooper Industries, and Kermit Lawson of Black and Decker for reviewing the text, adding information, and offering suggestions. Many thanks to my friend and typist, Michelle Jenkins, for her loyalty and timely meeting of deadlines. This book has been a labor of love intended to help improve the quality of the plastics’ injection molding industry and the parts it supplies to its customers.

The updating of quality methods for today and beyond was necessary to keep the information current with industry standards.

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M. JOSEPH GORDON, JR.

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Total quality process control (TQPC) for injection molding is an operation and quality analysis of the entire injection molding process. TQPC begins with customer involvement and continues through customer satisfaction. It is involved with all the major and minor equipment systems, material requirements, and operation and quality control requirements for repeatably producing good products in “real time,” cycle to cycle, to meet customer requirements.

The injection molding process is composed of a multitude of business and manufacturing networking support systems. The analysis begins by developing and understanding all the business variables operating in concert with the manufacturing variables, which include all the design and equipment variables that operate at the same time and that are necessary to produce a quality product. Combined with material handling systems, secondary assembly, and decorating operations (welding, electroplating, and printing) the product supplier must coordinate design and manufacture requirements with material, multiple machine operations, and support equipment and trained personnel for the process to produce a quality product for their customers.

All company operations begin with a well-designed quality program and process system that will encompass all the product and quality requirements necessary to produce a quality product in a repeatable operation. To support this task, the plastics industry is following the most current ISO 9000:2008 and automotive (section specific) ISO/TS16949:2009 quality standard system for
meeting their quality goals and customer requirements. A survey conducted
by the Independent Association of Accredited Registrars\(^1\) listed the main
reason for ISO accreditation as follows:

- 29% customer mandate
- 17% competitive pressure or advantage
- 16% continuous improvement based on customer requirements
- 14% improve own quality

To achieve good quality requires dedicated personnel, an executable quality
program with management support, and good documentation and communi-
cation between employees and the customer by communicating what you will
do, doing it, and documenting it. This requires that all personnel work together
as a highly motivated quality and manufacturing team to achieve TQPC
results.

ISO 9001

The implementation of a good quality program begins with quality documen-
tation as shown in The ISO Triangle of Documentation (Figure 1.1) for ISO
manual. The ISO accreditation program has additional requirements, which
include six procedures for specific documentation on how to handle control
of the following:

1. Documents
2. Records
3. Nonconforming items

4. Audits
5. Corrective action
6. Preventative action

Plus, the company can, if it deems it necessary, add any special and/or specific business and manufacturing operation procedures and operation-specific instructions to its system. Automotive, consumer, and aerospace companies have required their product suppliers to be in compliance and to be registered with ISO/TS 16949:2009 or AS9100, which demands more company quality documentation.

It is the responsibility of the company’s senior management to develop a quality program to assure customers that quality is their goal and that only products meeting their customer’s specifications will be shipped.

Even if a company does not become ISO certified, the company can use it as a guide in establishing a quality system. The quality manual is typically 30 to 35 pages with detailed, streamlined procedures and instructions for specific operations. Standardized templates are available on the Internet to be used as guides for all the documentation; a procedure example (Template) called “Control of Documents” is available in Appendix A.

I recommend a company document the individual and/or specific information and instructions for their equipment and process operations as individual instructions. The company can then record all data from its business and manufacturing operations into an established company program and project documentation and record storage and retrieval system. Such a system is called the molding data record sheet. Information on company operations is stored in this system. Documentation and operations data and records can be recorded at machine side for the individual injection molding machines in a molding data record sheet (Figure 1.2) and/or stored electronically in the file memory of the process control equipment setup instruction, which is downloaded into the configuration management system (CMS). Electronic storage is preferred as it will then be accessible at all stations with a computer operating with the CMS storage and retrieval system.

Documentation is necessary for each job setup because each mold and molding machine setup is specific and independent of all other setups that occur daily in a manufacturing environment. The molding data record sheet is a record of the specific settings used and of the process information on how the product was manufactured for the customer. It is based on the customer’s specifications as well as on the manufacturing setup instructions and records for how the product was produced. A copy of this information should remain as a record of the molding operation with a copy of the molds operation put in the program file. A lot of redundant information is filed, but it is necessary for a complete record of each item in the manufacturing operation. Remember, the next time the mold is run, it may be scheduled on another molding machine and set up by different technicians. These records assist in ensuring that the customer will receive the same product quality.
FIGURE 1.2. Molding data record sheet.
DOCUMENTATION

The quality program’s documentation process begins with the necessary company information and documentation, which is written as procedures and necessary instructions. These may be selected operations of the business, beginning with program initiation, design and development, manufacture, and service for the products provided to their customers. These instructions can be used as the basis for a company training program for new-hires and for training operators in performing additional and new functions. Keep documentation simple, to the point, and in a separate and easily accessible section of the configuration management system.

Information should flow from main documents, the quality manual and specific procedures, with any updating and revisions on the lower level documents as with your daily operating instructions and documentation. Machine setup and startup instructions can be laminated and located at machine side as an operation guide, in addition to any checklists and molding record sheet information.

Customer and program documentation also include information as meeting notes, verbal discussions, communications, and records produced during the customer’s program discussions and negotiations. Also, as the program progresses, the design, manufacturing information, and data are filed, respectively, in the CMS storage system.

Remember, the information and instructions not documented are quickly forgotten and may result in later problems requiring corrective action. Injection molding is one of the more variable intense manufacturing operations for producing a single product. Problems can occur quickly if a key variable is forgotten. And when a key person leaves, he or she can take information with them that was never documented on how a specific operation was conducted.

Process control is involved with determining, knowing, controlling, and documenting these variables as a record of the operation for the entire manufacturing process, step by step, from product design to shipping. This should also include all supplier information and support provided for product design and prototype assistance, if within the supplier’s capability level.

ESTABLISHING PROCESS OWNERSHIP

For any process to be successful, ownership must be assigned, accepted, and implemented within the organization. Ownership is defined as belonging to the one most to benefit from a successful program or well-running process. To determine who this, not always obvious, person is the following questions should be answered first. Who is the person with the most of the following qualities:
1. Ability to affect change
2. Resources (e.g., people, systems, and budget)
3. Problems (customer complaints, critiques, and endless defects)
4. Time available/necessary to make changes
5. Credit to gain when all works well
6. Actual or potential credit

The owner, as defined by this list of questions, should have the most to gain from these planned improvements. They should also have delegated authority to act, essentially, anywhere within the defined system, and even out of the supposed system operating area. Because the root cause of a problem may not always be in their direct line of authority, the leader must have senior management’s authority for the entire process. Responsible actions should always be coordinated through the managing authority in the other area if cause is found for the process problem originating from their actions.

I helped to solve a problem, at the request of the Vice President (VP) of Operations that was discovered at the final test point of their major product line. The solution involved an analysis of the product’s design, which involved multiple molds, assembly operations, and final testing. This problem had been occurring frequently for more than three years without a satisfactory and lasting solution. The final solution involved four departments and retraining assembly and test personnel after determining the multiple solutions that solved the problem. This problem was not in one person’s area of responsibility, but as in most cases, there was one person with the most to gain, in this case, the VP of Operations.

The business process owner should be given authority to operate at a level high enough to do the following:

1. Identify effects of any new business directions on the process
2. Influence changes in procedures and/or policies on the process
3. Plan and implement process changes as appropriate
4. Monitor the effects on the process for efficiency and effectiveness

The next set of criteria for effective process improvement involves the leader’s ability to lead. The team leader should possess leadership characteristics such as follows:

1. Recognition as a creditable leader in the company
2. Ability to direct and lead a group
3. Ability to keep the team on schedule
4. Ability to obtain the assets needed for support of the team
5. Ability to provide encouragement and direction for the team
6. Ability to induce change and have it accepted
7. Ability to deal and work with senior management
8. Reputation as a skilled negotiator
9. Ability to push aside roadblocks
10. Ability to live up to commitments
11. Ability to change poor performance into acceptable performance

It is best if the owner knows and understands the process. He or she does not have to be a member of management, but he or she is in many situations. The solution of a problem begins with a team selected for assistance. The process with the problem is then presented on a diagram or flowchart for the team to improve understanding of all the involved operations. It is then advised to run a failure mode and effects analysis (FMEA) with a fishbone in-depth analysis to uncover all variables that act on the entire process.

The FMEA is a step-by-step analysis of a process that lists all potential failure or problem points in the process and the results if not corrected or controlled. The fishbone analysis is a detailed analysis of a situation that lists all known variables that act on the situation. More in-depth information on the workings of these two quality methods will be discussed later.

Once all the available information of the process is known, analysis begins by making corrections, monitoring, and implementing preventive actions with the operation put back in service, corrected, and in perfect operation.

Five steps for achieving the TQPC goal are as follows:

1. **Standard selection.** Select the quality standard for the organization based on customer requirements and future business potential.
2. **Management support.** Management establishes the business goals, policy, and objectives and provides the ongoing assets and support.
3. **Corrective and Preventative Actions.** User satisfaction is first with the “root causer” of problems eliminated in all areas of the company.
4. **Continual improvement.** The quality management system (QMS) is continually reviewed, improved, and updated for quality performance.
5. **Know your system’s capability.** Maintaining your system’s equipment to a known standard is essential for repeatable manufacture.

The methods to achieve the quality required are not easy, inexpensive, or quick. Considerable time, money, and hard work are involved, which initially do not show a return on investment as quickly as management would like to achieve. Therefore, plan your quality improvement program well (checklists), use the information in this text as a guide develop your implementation plan in stages with check points and milestones for review of progress, and train

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yourself and employees in the methods and practices of achieving and retain-
ing a quality operation.

Work to ensure every employee can be the best he or she can be and provide the assets to have it happen. Have employees strive for repeatability of operations, with improvements as needed to reduce problems and cost, plus provide incentives for continual improvements in forms that are achievable by your personnel. Provide employees with the tools to do this, such as check-
lists, operation guides, instructions, procedures, and so on.

Review the classic quality methods for inclusion and consideration of use at your company. They may be old, but most are still active at progressive companies. Quality leaders have expressed their views that the Six Sigma advances were made using these “tried and true” quality methods listed in Table 1.1.3

To add some order to the quality area as far as methodology, what you see today is not really new; it is just presented in a different box. Quality essen-
tially started with control charting and progressed to what it is today. New names have been applied to proven methods.

Armand V. Feigenbaum’s *Quality Control: Principles, Practice, and Administration* (McGraw-Hill & Co., 1951) set the standard in 1951. His defi-
nition of total quality control (TQC) included the following plus many others:

- Design of experiments
- Quality cost
- Design review
- Statistical process control
- Process certification
- Involvement by top management
- Supplier controls
- Trained, certified quality engineers
- Reliability engineers
- Employee training

The next major change, which was implemented in approximately 1975, occurred with total quality management (TQM) and included the following requirements:

- All of TQC
- ISO 9001
- Benchmarking
- Team problem solving
- Five S

TABLE 1.1. Quality Improvement Methods.
Quality Methodology Understood:

<table>
<thead>
<tr>
<th>Program Name</th>
<th>Worker Involvement</th>
<th>Specialist Oriented</th>
<th>Group</th>
<th>Individual</th>
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ESTABLISHING PROCESS OWNERSHIP

- Toyota production system
- Strategic quality plans
- Lean
- Process focus

The TQM mantra is as follows: “Do it right the first and every time, no level of defects is acceptable.”

In 1984, the new program was business process improvement (BPI), which attacked the core of current white-collar problems by focusing on waste and bureaucracy. Quality output was the foundation with organizations simplifying and streamlining operations. The main objectives of BPI were to ensure the organization has the following business processes that:

- Eliminate waste
- Eliminate errors
- Eliminate delays
- Maximize use of assets
- Promote understanding
- Are easy to use
- Adapt to customers’ needs
- Provide a competitive advantage
- Reduce excess head count

Then in 1986, Motorola developed Six Sigma and focused on business improvement as consisting of the following:

- Understanding and managing customer requirements
- Aligning key business processes to achieve those requirements
- Using rigorous data analysis to minimize variation in those processes
- Driving rapid and sustainable improvement to business processes

The heart of the Six Sigma system is the methodology called “DMAIC” (define, measure, analyze, improve, and control process improvement). Six Sigma included the following:

- Selected TQM tools
- Selected BPI tools
- Full-time problem solvers called Black/Green Belts
- Expanded statistical training for a selected group of problem solvers

Tying all of the latest quality information together leads us to the current “Total Six Sigma” system. This came from the 1987 improvements of Six
## Standards & Practices of Plastics Molders

### Material
Acrylonitrile Butadiene Styrene (ABS)

**Note:** The Commercial values shown below represent common production tolerances at the most economical level. The Fine values represent closer tolerances that can be held but at a greater cost. Any addition of fillers will compromise physical properties and alter dimensional stability. Please consult the manufacturer.

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### Plus or Minus

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**REFERENCE NOTES**

1. These tolerances do not include allowance for aging characteristics of material.
2. Tolerances are based on 0.125 inch wall section.
3. Parting line must be taken into consideration.
4. Part design should maintain a wall thickness as nearly constant as possible. Complete uniformity in this dimension is sometimes impossible to achieve. Walls of non-uniform thickness should be gradually blended from thick to thin.
5. Care must be taken that the ratio of the depth of a cored hole to its diameter does not reach a point that will result in excessive pin damage.
6. These values should be increased whenever compatible with desired design and good molding techniques.
7. Customer-Molder understanding is necessary prior to tooling.

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**FIGURE 1.3.** Cavity hold tolerances, dimensionally.
Sigma, lean Six Sigma, and Total Improvement Management. The common bonds between these are the following:

- Top management leadership
- Process focus
- Similar problem-solving approaches
- Measurements of dollars saved
- Customer focus

The prime use of these methods is to ensure they are all applied correctly, never poorly.

When you begin a quality improvement program, research it so well you can explain it to your peers. Study the benefits that could be achieved and the time and cost of each method you may consider implementing. The Internet has a lot of free information on these methods that will give you a brief overview as to what they can accomplish when applied correctly. I have used several that returned considerable quality benefits when implemented. I believe in using statistical process control (SPC), fishbone analysis, quality circles, FMEA, checklists, equipment and process procedures, and instructions. The Lean and Six Sigma methods are discussed and have considerable merit when correctly applied by a trained implementer.

Total quality process control is composed of a QMS, trained personnel, and management support systems to ensure all customers’ specifications (within injection molding capabilities) are achieved. This means that metal working tolerances are not used for plastic parts. Tolerances, both fine and commercial, for the manufacture of injection molded plastic products, in this case, for the unfilled plastic material acrylonitrile butadiene styrene (ABS) as documented per the Society of the Plastics Industry, Inc. (SPI), are shown in Figure 1.3. Each generic plastic has its corresponding tolerance value variance figure available from the SPI.

The tighter the tolerance requirement, the greater the cost of the product because the manufacturer will have to hold tighter tolerances in a variety of molding areas from the choice of designing the part, material, mold design, molding parameters, post cure, part assembly, and handling methods.

**IDEAS AND METHODS**

When the ideas and concepts for creating a TQPC program are accepted by all levels of an organization, the result will be profitable products for the customer. The TQPC program effectively completes the customer-supplier design and manufacturing cycle by focusing on development of a

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4http://www.statsoft.com/textbook/stquacon.html#process.
quality-conscious organization for product development that covers design, material selection, tool design, and manufacturing through assembly and decoration, to the final shipment of the product to the customer.

It is best to use statistical process control methods to supervise the manufacturing of plastic parts. Unlike earlier statistical part checking methods, TQPC does not rely on inspection to separate the good from the bad parts. Rather, from the start, it focuses on all the variables that can influence plastic part manufacture. Success is achieved through a combination of good design principles, the use of capable manufacturing equipment, and appropriate selection of part tolerances, materials, and tooling. Finally, the manufacturing process must be controlled to meet customer requirements.

In no-nonsense terms, TQPC explains tried-and-true methods that work and ways to motivate the organization to accomplish the common goal of product quality. The plastics injection molding industry has long needed this type of information, which ties all the many product and manufacturing variables together in an organized and readable format.

Many companies already using these methods are reaping the rewards by becoming preferred suppliers. As a result, they are continuing to grow in a very competitive marketplace. In fact, most companies, from large original equipment manufacturers (OEMs) to small part suppliers, which now use these principles, can with a little more effort and practice become even better quality-product suppliers and more competitive in the marketplace.

Readers who apply TQPC methods will find them easier to implement than had been thought earlier and, through a good program, can achieve even greater returns at minimum cost while expanding their customer bases.
Implementing Total Quality Process Control (TQPC)

TQPC uses the quality methods developed by the quality leaders including Juran, Deming, Taguchi, Feigenbaum, and others to develop a system where the best quality methods are used for control of the design, development, and manufacturing processes. Based on today’s quality leaders who suggest that the lean style of manufacturing is best, non-batch style of production, TQPC strives to meet this type of production. If it is not capable of meeting production for the batch style of manufacture for injection molding, then it will be productive in later operations as during the decorating, assembly, and final testing of finished products in the original equipment manufacturers (OEM) plant.

Products produced today are not allowed to have an acceptable amount of defects, as with the acceptable quality level method of manufacture and quality inspection, which is illustrated in Table 2.1. Today, management wants all their parts to be in the acceptable category, without any defects. This is possible with TQPC when all variables remain in control and instructions are followed. This zero-defect type of manufacture ensures all variables are in control and are kept there during the entire production run. This is not easy to do but is a goal to achieve.

A “quality improvement plan” with step-by-step instructions lists the steps for the implementation of improving quality with minimum effort. Quality can always be improved when the quality team “accepts the challenge.”
| Lot Size     | Sample Size | 0.25 | 0.5 | 0.75 | 1   | 1.5  | 2    | 3    | 4    | 5    | 6    | 7    | 8    | 9    | 10   | 12   |
|-------------|-------------|------|-----|------|-----|------|------|------|------|------|------|------|------|------|------|
| 499 or less | 40          | A    | R   | A    | R   | A    | R    | A    | R    | A    | R    | A    | R    | A    | R    | A    |
|              | 50          | 0    | 2   | 0    | 2   | 0    | 3   | 1    | 4    | 1    | 4    | 1    | 6    | 2    | 6    | 2    |
|              | 60          | 0    | 1   | 0    | 2   | 0    | 3   | 1    | 3    | 1    | 4    | 2    | 5    | 2    | 6    | 3    |
|              | 70          | 1    | 3   | 1    | 3   | 1    | 4   | 2    | 5    | 3    | 6    | 4    | 8    | 5    | 9    | 5    |
|              | 80          | 2    | 3   | 3    | 4   | 3    | 4   | 4    | 5    | 6    | 7    | 8    | 9    | 8    | 9    | 9    |
| 500 to 799  | 40          | *    | 1   | *    | 1   | *    | 2   | *    | 0   | 3    | 0    | 3    | 0    | 4    | 1    | 5    |
|              | 60          | *    | 1   | 0    | 2   | 0    | 3   | 1    | 4   | 1    | 5    | 2    | 6    | 2    | 7    | 3    |
|              | 80          | 0    | 2   | 1   | 3   | 1    | 4   | 1    | 5   | 1    | 6    | 3    | 7    | 3    | 8    | 5    |
|              | 100         | 0    | 2   | 1   | 3    | 2    | 4    | 2    | 5    | 2    | 6    | 4    | 8    | 5    | 9    | 6    |
|              | 120         | 1    | 2   | 2    | 3    | 3    | 4    | 4    | 5    | 5    | 6    | 7    | 8    | 9    | 10   | 11   |
| 800 to 1,299| 40          | *    | 1   | *    | 1   | *    | 2   | *    | 3   | 0    | 3    | 0    | 4    | 0    | 5    | 0    |
|              | 60          | *    | 1   | 0    | 2    | 0    | 2    | 0    | 3    | 0    | 4    | 1    | 5    | 1    | 6    | 2    |
|              | 80          | 0    | 2   | 0   | 2    | 0    | 3    | 1    | 4    | 1    | 5    | 2    | 6    | 2    | 7    | 3    |
|              | 100         | 0    | 2   | 0   | 2    | 0    | 3    | 1    | 4    | 1    | 5    | 2    | 6    | 3    | 8    | 5    |
|              | 120         | 0    | 2   | 1   | 3    | 1    | 3    | 2    | 5    | 2    | 6    | 3    | 7    | 5    | 9    | 6    |
| 1,300 to 3,199| 50       | *    | 1   | *    | 1   | *    | 2   | *    | 3   | *    | 3    | 0    | 4    | 0    | 4    | 0    |
|              | 75          | *    | 1   | *    | 1   | 0    | 2    | 0    | 3    | 0    | 4    | 0    | 5    | 1    | 5    | 2    |
|              | 100         | *    | 1   | 0    | 2    | 0    | 2    | 1    | 4    | 1    | 4    | 1    | 5    | 2    | 6    | 3    |
|              | 125         | 0    | 2   | 0   | 2    | 0    | 1    | 3    | 1    | 4    | 2    | 5    | 2    | 6    | 3    | 7    |
|              | 150         | 0    | 2   | 0   | 2    | 1    | 3    | 2    | 5    | 2    | 5    | 3    | 7    | 4    | 8    | 6    |
|              | 200         | 1    | 2   | 1    | 2    | 2    | 3    | 4    | 5    | 5    | 6    | 7    | 8    | 9    | 10   | 11   |

A — Acceptance number; R — Rejection number; * No acceptance at this sample size.
Arrows: When there is an arrow under a given AQL, use the first sampling data below the arrow. (Form larger lots if possible.)
Adapted from Ref. [1].
QUALITY IMPROVEMENT PLAN

1. Company management commits to improving quality.
2. Management team appoints a “leader” to undertake quality improvement, with accountability.
3. Leader forms a quality team to determine the degree of quality improvement and where to begin.
4. Determine needs by monitoring the areas of the operation that need improvement from problems.
5. Select the quality system/accreditation and methods to use for determining the system to select.
6. Examine system for “root cause” of each problem detected.
7. Document all the results of the problem definition and analyze the problem for root cause and repeatability.
8. Discuss the requirements with personnel involved for each problem and document all possible solutions.
9. Develop possible solutions for problems with confirmation that the solution is correctly implemented, monitored, and proven to eliminate the problem without causing a new problem.
10. Write new update existing manufacturing/service procedures and instructions, train personnel, and implement them.
11. Conduct quality failure mode and effects analysis (FMEA) operations for monitoring the business and manufacturing operation.
12. Develop and implement procedures and monitor them in real time for operation.
13. Develop checklists for all operations to establish repeatability of operations.
15. Monitor operations for quality business and manufacturing operations.
16. Use quality function deployment (QFD) methods with the customer to develop better information to meet their requirements.
17. Implement ISO 9001:2008 or beyond for operations and customer quality.
18. Monitor and maintain manufacturing equipment for compliance with manufacturer specifications of operations.
19. Monitoring operations for data accuracy to meet customer and internal quality requirements.

These are the starting methods to use when performing quality improvement, no matter what quality system is used in your company.
TQPC focuses on the “total manufacturing system,” not just the molding machine. In an analysis, the injection molding machine is just one of many variable-producing mechanisms that the manufacturing system must keep in control. When all the major variables are considered, such as material, control systems and auxiliary equipment, mold, plant environment, and maintenance services, there are a sizable amount of variables that need to be controlled.

There are, then, the secondary operations to consider for the part, such as assembly, decoration, information transfer, and any other operations required of the parts end-use service. An example of this is shown in Figure 2.1 in a partial fishbone diagram of some molding variables.

Note that as one main element is identified, there are support variables that contribute to the main elements actions on the total process or item, as selected for analysis. Always take each element to its basic factors so no single item is ever left unidentified in the analysis process. If necessary, take it to the supplier of an item, as the problem could have originated in their system, and was not told to your personnel.

Unfortunately, some suppliers do not inform their customers of all changes they may make in their products. They often assume the change is so minor it will not matter, or it is proprietary and need not disclose any changes as long as the end use is not affected. But this is not always the case. Therefore, create a trust with your suppliers to ensure, if they ever modify their product, to disclose this information and require that they send a trial sample for evaluation before the change is actually made. This will give you time to evaluate the modification in your product for processing and end-use performance.

FIGURE 2.1. Fishbone diagram.
STATISTICAL PROCESS CONTROL (SPC)

SPC is used to gather statistical control data for your operations. An example includes the data gathered to measure the degree of control [capability (Cp)]; thus, a machine, process, and/or operation can reach and then maintain this level of productivity during manufacture. Because injection molding at a custom molder is a typical short-term program, the parts required for the customer must be produced, in a specific time period, and shipped. Then, change the molds and begin the next program, possibly with a new material and different customer quality requirements for the product. The important item to remember is that the quality program does not change; only the mold, machine settings, and material at the machine will change.

Many injection molding machines have the SPC “closed loop, continuous feedback machine controls,” which continuously measure the variance in machine process and/or product during each machine or molding cycle. If a variance is noted, depending on how the control system is set up, it automatically attempts to adjust the affecting variable to keep the process in control, using pre-assigned control limit values of adjustment, to reestablish the specific control parameter, sensed, out of tolerance.

If a variable seems to change the process, the SPC control system attempts to correct for the variance. If the variance is too great or continues out of control and crosses over the established upper specification limit (USL) and/or lower specification limit (LSL), an alarm will sound calling the machine operator’s attention to adjust the machine manually or determine what has changed to cause the dramatic out-of-control problem. The change could be minor or major depending on the “root cause” of the problem.

Today, statistics are used to determine and control those areas of strength in a manufacturing system that can be used to improve the total system for manufacturing plastic products. Statistics are a very useful tool for controlling the manufacture and monitoring the quality of plastic products.

CONTROLLING THE PROCESS

In any manufacturing process, it is extremely important to maintain the highest degree of process control. Injection molding is dependent on a cycle-to-cycle repeatability in process control. It is also very important to know whether the process equipment can maintain the type of control required to produce good parts repeatably.

It is a statistical fact that when the Capability Index (Cp) of a process or system is 1.00 or greater, the variables in the process being monitored are in control during the period of time they were monitored. Therefore, monitoring Cp is one of the key quality operations that show whether the system and all the supporting branches are in control for that time period.
IMPLEMENTING TOTAL QUALITY PROCESS CONTROL (TQPC)

The centeredness of the curve indicates the degree of control of the machine and/or process when the data are plotted as shown in Figure 2.2. Equipment and software systems are available to perform the data collection, analysis, and plotting automatically to show the degree of control within the monitored system. The spread of the ends of the curve indicates the degree of centeredness or control of the system. As the curved ends of the data spread beyond the USL/LSL, the result is a direct reflection on the control of the process, either high or low.

FIGURE 2.2. Cpk is a measure of spread and centeredness; the higher the Cpk value, the more in control is the process.

The centeredness of the curve indicates the degree of control of the machine and/or process when the data are plotted as shown in Figure 2.2. Equipment and software systems are available to perform the data collection, analysis, and plotting automatically to show the degree of control within the monitored system. The spread of the ends of the curve indicates the degree of centeredness or control of the system. As the curved ends of the data spread beyond the USL/LSL, the result is a direct reflection on the control of the process, either high or low.

CP THE CONTROL OF OPERATIONS

It is recommended that each time a mold and injection molding machine combination is used, a Cp system analysis is conducted. This will show when the operation reaches equilibrium with the system’s operating variables. As monitoring continues, it will validate the control the process is capable of obtaining to produce good parts, with the data recorded for process control. If needed the data can be given to the customer showing the degree of control achieved during their product run. This is explained in greater detail in the author’s book from J. Wiley & Sons, Industrial Design of Plastic Products.

The processes cycle’s Cp index is used for determining the capability of the system for continued repeatability of the manufacturing operation. It is also
used to determine how tight the processing tolerance must be held so acceptable parts are achieved on every cycle. Monitoring the cycle and process variables in real time is critical to ensure the parts stay within acceptable process parameters. Typically, the injection molding machines’ main variables, pressure, temperature, and timer settings are monitored for cycle consistency, which results in the machines Cp value. A capability analysis will also provide management with a good analysis of the quality of their “preventative” maintenance program, or if one is necessary. The Cp is generated on operation data and analyzed during the startup and continued molding of the product for consistent repeatability.

To assist in determining the Cp value of the machine, most injection molding machines and support equipment come with the option of having real-time process control systems installed on the equipment. The machine manufacturer provides the options of what is installed on the machine, often at the buyer’s suggestion or selection. The better the control system, the better the output of the machine.

TQPC is involved in maintaining the highest degree of process equipment capability by monitoring the machine and system’s index of capability, either Cp, Cpk, or Ppk. (Cp is the ability of a process to produce consistent results, Cpk is a capability index for how well a system can meet specification limits, and Ppk is an index of longer term process performance for how well a system is meeting specifications.)

Cp is the ratio between the permissible and the actual spread of a process. Permissible spread is the difference between the USL and the LSL of acceptability or the total tolerance, where the actual spread is the difference between the upper and lower 3 × σ deviations from the mean value (representing 99.7 percent of the normal distribution). The formula is \( Cp = \frac{USL - LSL}{6 \times \sigma} \).

Note: In some cases, the term “specification” is replaced with “control”, I have used specification here.

In statistics, sigma (the lowercase Greek letter \( \sigma \)) is defined to represent, the standard deviation (a measure of variation, http://en.wikipedia.org/wiki/Standard_deviation) of a population based on a sample. Its units of measurement are dependent on the selected sample, which is defined as the square root of the variance. In a capability/study, sigma refers to the number of standard deviations between the process mean and the nearest specification limit as shown in Figure 2.3, with the mean at 0 and the specification limits at ±6 sigma.

To understand standard deviation, remember the variance is the average of the squared differences between the data points and the mean. Variance is tabulated in units squared. Standard deviation is then the square root of that quantity that measures the spread of data about the mean, measured in the same units as the data.

As an example, in a population of (4, 8), the mean is 6 and the deviations from the mean are (−2, +2). These deviations squared are (4, 4), the average of which (the variance) is 4. Therefore, the standard deviation is 2. In this case,
100 percent of the values in the population (4, 8) are at one standard deviation (2) from the mean.

Formally stated, the standard deviation is the root mean square (RMS) deviation of values from their arithmetic mean. Cp (process capability) can be thought of in the following ways:

- Cp measures the capability of a process to meet its specification limits. It is the ratio between the required and the actual variability
- Mathematically, the Cp is expressed as $C_p = (USL - LSL) / (6 \times \sigma)$. This is the spread of a normal curve. Capability statistics are basically a ratio between the allowable process spread (the width of the specification limits) and the actual process spread (6 sigma)
- Graphically, as shown in Figure 2.4, a normal curve is centered between the specifications. Notice the tail-end areas that exceed the specification limits. The smaller the area outside the specifications, the larger the Cp. This is similar to looking at a parts per million (PPM) value for the number of items that exceed the specification.
CPK-CENTERED PROCESS CONTROL

Cpk or the process capability index is a measure of the off-centeredness of a Cp-centered process producing a similar level of defects—the ratio between permissible deviation, which is measured from the mean value to the nearest specific limit of acceptability, and the actual one-sided $3 \times \sigma$ spread of the process. As a formula, $Cpk = \begin{cases} \frac{(USL - \text{Mean})}{3 \times \sigma} & \text{or} \\ \frac{(\text{Mean} - LSL)}{3 \times \sigma} & \end{cases}$, whichever is smaller (i.e., depending on whether the shift is up or down). Note that this ignores the vanishing small probability of defects at the opposite end of the tolerance range. A Cpk of at least 1.33 or greater is the desired value.

Note: Do not connect the term “Six Sigma Process” as the same as $(6 \times \sigma)$, which is the process control charting of Cp and Cpk. They are not the same!

Process control includes the following:

- **Documentation**—Documenting what you say you will do, how you will do it, and how you will ensure or enforce it being done each and every time.
- **Training**—Provided to ensure it is always done correctly.
- **Process monitoring**—Real-time monitoring and instant feedback of process variables and machine status, along with access to real-time process data uploaded to remote computer terminals with alarms for out-of-tolerance conditions.
- **Data entry**—Operators enter downtime reasons and update work order status, part production, and scrap information in real time for production control at the press.
- **Automated graphical reporting**—Machine uptime and production reports to reduce burden on resources and provide timely access to information with graphic run charts provided for tolerance control capability and either operator/computer determining or maintaining machines and system at optimum Cp efficiency.
- **Instant notification**—E-mail and paging notification immediately alert decision makers of machine, plant, and equipment status and of molding process variations.
- **Diagnostic tools**—Tools available for determining root cause of problems associated with equipment and system control and operation when out of tolerance conditions occur.
- **Advanced features**—Depending on software selected, most allow modular architecture to add modules as their needs grow. Optional modules enable

\[\text{Search for “Process Capability Cp” on the Internet or go to http://en.wikipedia.org/wiki/Six_Sigma for additional information.}\]
production tracking, advanced planning and scheduling, as well as statistical process control.

The use of pure statistics, however, will not impart quality to a product, but it can identify where problems exist and quantify the type and frequency of occurrence. Separating the acceptable from the nonconforming is costly, but in some situations, to get the product to the customer, suppliers have resorted to this method of manufacture. When this occurs, identify the defects and their percentages with Parato charts (Figure 2.5), which report on the frequency and type of nonconforming items produced. This will give emphasis to providing a solution to this problem. When this is recognized and acknowledged, then corrective action can be employed.

Likewise, employee quality groups, such as quality circles, will not prevent poor designs and tooling in the manufacture of products, and zero-defect commitments cannot solve machine capability problems that produce bad parts. What is needed is management commitment to providing the quality resources, equipment, personnel, methods, training, and to ensure motivated and trained personnel properly apply these assets. This commitment to produce only quality products must start with senior management and continue down the lines of authority in the company. A quality circle group, newly implemented, at a major Japanese automotive company saved more than $75,000.00 by implementing preventative problem solving solutions in their department in one year.

Quality improvement must be the goal of all employees, from senior management personnel to the shipping clerk. All operations of a company affect the quality of the final product and service to the customer. Customers

![Parato chart of defect types.](image-url)

FIGURE 2.5. Parato chart of defect types.
have come to anticipate that only quality products are shipped to their receiving dock, which can go directly to their assembly line, often without inspection. This puts the responsibility where it belongs, on the supplier of the product.

This is the “Do it right the first time” mantra that management must send to their employees with the support and training they need to do it. Customers are reducing their supplier base and relying on their proven and quality-minded suppliers. Customer attitude is not based solely on unit price also but depends on their cost of handling the unit once it has been received at their plant and a problem is found. The cost is now almost doubled because of their required incoming inspection cost plus the loss of the unit and their time loss waiting for a replacement.

**ESTABLISHING COMPANY QUALITY OBJECTIVES**

Quality objectives should be a reach for a company. The objectives must be attainable within the scope of the company policy, yet a goal that is not easily obtained. Management must be kept alert and always searching for new methods for improvement, including how to do it better while providing more value, for the customer, for the price charged. Quality is always defined as “customer satisfaction.” What is important is how to satisfy customer requirements while justifying costs and earning a profit. The “best” in relation to quality control means satisfying the customers needs and wants within part requirements and cost structure.

For a company to commit to TQPC, it must first ensure it has the internal structure on which to build the quality system. Second, it must take the time to write down, first their short-term and then long-term, business, financial, and quality objectives. The company should believe it will be capable of meeting these requirements; then, it should implement the structure to accomplish this requirement. The objectives should meet the needs and expectations of company management and customers. Objectives should be straightforward and to the point.

1. Ensure that the guide for establishing the company’s goals is the company plan, with departments selecting their individual yearly objectives for meeting their goals and making their operations more error and problem free.
2. Separate management and quality for independent operation. Ensure joint agreement on the supplying of assets for customer satisfaction.
3. Ensure all employees are aware of their customer’s product requirements. Sales using QFD (discussed in Chapter 3) will develop information for determining and establishing the customer’s wants and needs beyond the current product.
4. Ensure the products’ design, manufacture, and end-use requirements are known and established by the customer when design is involved for the product. Use checklists specifically designed to gather all the information required for the product and its manufacture.

5. Establish preproduction reviews with all involved departments to ensure all details, specifications, and requirements are established and questions are answered.

6. Establish the manufacturing requirements, equipment dedicated, and suppliers of materials selected and approved with manufacturing instructions written and an FMEA conducted to ensure all variables and potential problem areas have been considered and evaluated.

7. Select suppliers who can provide the products and services necessary and within the specifications and price required for the products. Both response time and customer service are critical for injection molding because of the variety of products and materials used daily.

8. Daily process control measures for maintenance of equipment is mandatory, as equipment is often used in a variety of manufacturing conditions and its maintenance and cleanup after each job is critical to avoid the cross contamination of materials. Vacuum up material; never blow it!

9. All data generated must be used in real time. Data collected during a process reaching equilibrium is historic data. Only when the system has reached “temperature equilibrium” should adjustments to the cycle be made.

10. Always observe the cycle and give it time for an adjustment to be incorporated into the operation. Too many hasty adjustments can create cycle instability and have it go out of control. It is very critical for control of the process to maintain control of the entire operation. Be sure the data collected are meaningful and are analyzed right away.

11. Train personnel to use checklists, process sheets, and instructions during their daily work operations and to follow established procedures. Maintain operation sheets and run/log books with mold and machine operation conditions. Keep equipment maintenance records at the machine for reference and to know the items on the machine, screw and nozzle type, age of heater bands, and so on.

12. Recognize quality as a price necessary to pay for the product, not as a negative cost. Quality is essential for product and process and must be instilled in personnel as a necessity, not as a requirement. A goal is to have the price of quality less than 2 percent of sales. Keep quality as a positive company and department quantity!

13. Make corrective action a thing of the past and inspire preventive actions to identify, correct, and eliminate problems from the business and work area. Be proactive in daily maintenance and quality operations.
Success will result when you manage your area of responsibility as if you own it. You take the responsibility to ensure all is correct and processes are in control and remain within specifications.

CUSTOMER QUALITY

Customer quality requirements should not vary within the organization. Each customer’s product is special and is manufactured using the same methods as any other product. When quality procedures are written, all jobs will require the same degree of supplier quality and with a well-established and managed system in place, all job objectives and requirements will be successful. The only recognizable feature will be that some jobs may have tighter specifications; your company will be capable of meeting these specifications on a daily schedule.

To consider having a tiered quality system is wrong. The company should only produce products to their best capability. The only difference is what the customer requires for their product’s finished state. This is determined when the program is contracted and quality is discussed with the customer. No variance in quality operations should ever be allowed. List on the program setup sheets what the customer requires, not what the customer will accept!
Management must commit to producing a quality product! Without this commitment, it will not happen. This statement of quality excellence must be included and attainable in the company’s policy statement and communicated to all of the employees.

**OBJECTIVES FOR MANAGING A QUALITY SYSTEM**

A well-organized and documented total quality process control (TQPC) system must meet the following objectives:

1. Positive customer orientation
2. Well-defined and specific quality policies and objectives
3. Departments and personnel oriented to achieving these objectives and carrying out the policies
4. Specific vendor control policies
5. Complete and identified part and process quality requirements
6. Full documentation of work instructions for operator use
7. Trained personnel with motivated and strong quality knowledge
8. Proactive preventative problem analysis program
9. Continuous real-time process control with closed-loop, self-adjusting control of process parameters, if not, operators capable for control
10. Periodic audits of process systems for compliance to specifications

Quality encompasses all departments of the company. Sales and marketing promote and obtain sales of the company’s products and/or services. They are the first contact your customers have with your company. Your customers’ first impressions of your company are key along with ethical control of your business dealings with their company. Honesty, integrity, and quality make up a trio of reasons for conducting business. Honesty in providing the services at a fair price, integrity in providing the service as contracted, and quality in the provided service that meets with the customer’s satisfaction. In between these actions are a multiple of required actions that will make the business relationship a success.

Management has responsibility for 85 percent control of the quality system, but it manages only 15 percent of the process. Management must be made aware of the assets needed and provide them in a form usable in their operations. Once a quality system is established and operating, they must support it and ensure it provides the services necessary to execute the actions needed for providing quality products and services to their customer base.

The first principle management must be aware of is: “Quality is never your problem, it is the solution to your problems.” The price of ignoring quality has cost major corporations their loyal customers. Rival companies are waiting to compete and provide the products customers want with the quality consumers have been wanting, so the customer can purchase the product. Customers are willing to pay for quality when it is in the product and/or service.

The cost of ignoring quality has brought new competitors into their markets. Many have proven to themselves that a staggering 20 to 25 percent of a company’s operating budget is spent fixing problems that should never have occurred.

**PROACTIVE PREVENTIVE ACTION**

Learning how to identify potential problems is the key to proactive preventative action. Identifying a potential problem before it occurs is one of the correct ways to spend quality assets. TQPC is dedicated to this means of identification of preventative problems. Will all of them be detected before manufacturing begins? Probably not all, but most will when the methods described here are implemented, practiced, and used daily. These methods are not difficult, but they must be followed and used to achieve the best results.

Providing the right working environment, equipment processes, assets, and people is the key to a successful TQPC program. Management must be held accountable and its performance measured by how well the company
provides the support and assets necessary to achieve the quality goals. Management must be involved in more than name. The management quality objectives should be made known to and judged by all employees to determine whether they are committed and serious about obtaining their stated objectives.

Quality must become a way of work ethics. It must start with senior management and proceed down to all levels of employment in the company. Plans must be developed as to how this is to be done. All programs must have a good plan to succeed. It is also important to keep it as simple and as practical (worker friendly involved) as possible. It is interesting to note that when quality-control circles were first developed in Japan, management believed they were a waste of time and were initially reluctant to implement them on the factory floor.

Today, typical areas explored by the quality circle volunteers, usually up to ten plus their leader, are ways of improving safety, product design, and the manufacturing process. Quality circles have the advantage of continuity; the circle remains intact from project to project. Savings can be great, up to $100,000.00 and greater when correctly applied in the work place.

In their plan, management personnel must establish objectives for each type of service and product it wants to provide to their customers. These products and services include the assets, machinery, and equipment to make the product; the people to design and manufacture the product; and the sales team to solicit and service accounts, as shown in the ladder of operations (Figure 3.1). This progression of operations and specific actions must occur for the program to precede to completion. The manner in which these operations are performed includes the objectives of the TQPC plan. If one area in the plan should be faulty, then there needs to be a method of immediately making the correction to ensure continuation of the process.

TOTAL QUALITY PROCESS CONTROL

Attitude

All quality programs require a positive attitude toward accepting change in the organization. Just because it was always done one way for years, does not mean it cannot be improved. A positive searching attitude of new ways to do and improve the business is healthy for a business to instill in their employees. Remember, most quality methods were developed in the last 50 years by employees of very successful companies (e.g., Western Electric, Motorola, General Electric, Ford Motor Company, Toyota Motor Sales, and others). These companies fostered a growth in quality methods and improvements by changing the manufacture and quality of their operations.

Management provides the driving force for these operations to happen. They must also practice and support these quality operations even if the return
is not always as great as anticipated. Remember, the Six Sigma quality programs were only initiated if the potential savings were identified as being $175,000 or greater and then required senior management approval. A designated management champion was then assigned to spearhead the program and ensure it had all the assets necessary for a positive result. In the beginning, that was not always achieved. Within Motorola, which is the developer of Six Sigma, the program leader, to become a designated Black Belt, had to manage a successful program of about $175,000 of savings to earn the title. As we know, not all programs can yield this amount of savings. Therefore, as the system spread, the monetary requirements were lowered to create more Black Belt quality experts within all sizes of companies. Unfortunately, this has turned into a money-making industry, as one organization for Six Sigma training advertises that two separate weeks of training and one project sandwiched

\[ \text{FIGURE 3.1. Ladder of operations. The lean method of manufacture works in a similar fashion, which will be discussed later in the text.} \]

\[ \text{\footnotesize Six Sigma. Available at: http://en.wikipedia.org/wiki/Six_Sigma.} \]
in between equals the Black Belt. This format is not exactly what the initial program had in mind!

There are now many Green, Black, and Master Black Belt quality professionals within all sizes of companies with multiproduct diversity who are making major quality contributions to the success of these companies. Are their programs capable of attaining the same size savings and rewards? Probably not, but they are improving their companies’ quality operations.

Control of Change

Improvement requires change to occur within an organization. The intent is to have a positive result, not to change because everyone else is doing it, as it is not always successful. Change can be as minor and simple as improving the lighting in the business and manufacturing areas. Light improvements have shown to increase worker output by over 35 percent in some companies. The work area must be as pleasant as possible, and it is a quality item for future consideration.

Improvements should be explained to the employees when changes are going to be required. It is helpful to explain why they are being made, the expected result, the benefits to them and the company, and what time, effort, and their involvement may be necessary. Whether any employees are to be moved, retrained, transferred, and so on has to be explained to alleviate fears of loss of jobs and smooth the transition when employees are moved within the company.

When a Kaizen, a fast work area improvement quality method, is performed, some employees may no longer be required to perform operations that were combined or even eliminated. They are not fired or laid off but are used in other areas of the operation, especially if long term, loyal, and knowledgeable in operations. Keep the pain of change low and the achievements to be gained from improvements high.

Also, investigate the anticipated effects of improvements even before they are made to ensure their effect will not cause a problem after the change. Plan the improvement, analyze the changes to be made, make the change, perform a failure mode and effects analysis (FMEA) if possible, and analyze the results. Last, ensure management agrees with the changes and will lead the improvement program, providing the incentive, support, and assets for it to be successful. Training is essential for all personnel especially if new operations are implemented. A trained employee pool is essential for a successful program starting up with minimum difficulties. It is also essential that management listen to their employees as they may have some positive input into the planned changes that will dramatically affect the success of the program. The use of a quality circle type of analysis is helpful in planning the changes, anticipating what problems may occur, and reviewing the amount of training and new instructions that are required to ensure the program is successful and has a positive startup.
**Improvement with Control of Change**

To implement change accurately, planning is essential. The requirements, equipment, their installation, training of personnel, and trial startup runs must be written down in detail to be sure the results are attained with good product output rate. There are numerous analysis results to be evaluated for all situations, and fine tuning may be necessary to obtain the best results.

An example may be a decision to move to quick mold change by preheating the molds. This involves an analysis of the following:

1. Justification (savings in time and product gain) of going to quick mold change
2. Molds and what machines they fit
3. Machine platens and molds modified for quick change
4. Availability of preheating equipment
5. Platen insulated from mold
6. Procedure and checklists to heat, install, and start up the mold
7. Access of lifting/installation equipment to install mold
8. Instructions written and trialed at press
9. Setup team trained in quick change methods
10. Molding machine considerations, material staging, clean out, and so on.

When a new idea finally becomes reality, considerable planning and work is done to ensure that if the change is made, it is justified and can be accomplished.

Documentation is the key, and recording of all events is necessary. The startup of a new molding cell, operation, or machine requires verification of required operations using, in my experience, a checklist of items that have to be accomplished so the operation would be successful. Even the omission of one item could cause the results to not be positive. I have been involved in troubleshooting multiple problem areas that were never solved until an analysis of the data and a set of in-detail instructions led to the final solution of the problem.

Keep good records and review the recorded information generated from the operation in real time—not an hour later but immediately after it was recorded so it can be used in the control of the process. If a problem should persist and a solution is not be possible, then shut down the operation, review the data, make a calculated analysis, or decide to run a “design of experiments” (DOE) (see Appendix B for an example) to determine the variable(s) that are the main contributor of the problem. See the Engineering Statistics Handbook (http://www.itl.nist.gov/div898/handbook/index.htm).
Quality Decisions

Decisions are made on the best information available at the time, and often a decision should not be made until additional information is obtained, which is a decision. The gathering of information begins with the sales department and spirals upward in the organization processing through each department that is affected by the operation. Each department requires a specific type of information to assist in its decision-making process of the order, and it affects the quality of the operation/product and the profitability of the operation.

During all phases of operations, the customer is continually evaluated for attaining satisfaction, which is the goal of quality operations. Flexibility is often required in design or manufacture, and the individual departments must share their knowledge and experience to attain the best possible results. Using measurable results and feedback, the system must adjust to new factors as they occur. You want to avoid fragmentation within the quality organization and to keep all departments working toward the common goal of quality.

PRINCIPLES FOR QUALITY SYSTEMS ENGINEERING

The principles that relate to quality systems engineering are as follows:

1. Relate quality technology to quality requirements through hardware, procedures, and plans to meet customer needs.
2. Relate quality technology to quality requirements by evaluating new and changing systems. Balance technology with these requirements, thereby guiding the introduction of practical improvements in the quality system.
3. Consider the total range of relevant human information and equipment factors needed for these procedures and controls. Integrate hardware–human–equipment–information factors as a functional system.
4. Using feedback, measure and fully evaluate the quality system in operation. Establish measurements to grade the system.
5. Quality systems engineering should structure the quality system objectively and provide for audits of the system.
6. Provide for the ongoing control of the quality system by combining quality systems engineering and management.

OBJECTIVES FOR MANAGING A QUALITY SYSTEM

A strongly engineered and well-managed total quality control system must meet the following objectives:

1. Positive customer orientation.
2. Well-defined and specific quality policies and objectives.
3. Departments oriented to achieving these objectives and carrying out the policies.
4. Integration of company departments to produce quality products.
5. Clearly defined personnel assigned to achieve quality.
6. Specific vendor control activities.
7. Complete and identified part and process quality requirements.
8. Defined and effective quality information records, flow processing, and control for manufacture.
9. Well-trained company personnel who are motivated and strongly quality minded.
11. Positive corrective action procedures that will be effective.
12. Continuous control of the system with feedback and flow of information so that the analysis of results can be compared with present standards.
13. Periodic audit and checking of systems activities.

No efforts should be spared to produce a new part or evaluate an existing part prior to production. No new job should be accepted without an extensive evaluation of all these parameters. But, in many cases, for parts with existing tooling (the common industry term referring to the mold base and part cavity), if the tool is transferred to a new molder or part supplier, this is never done. As a result, the existing part and tooling problems for the old supplier become the same problems for the new supplier.

A lower piece-part price is not always the driving reason for tools to be moved to a new molder. Usually, the decision is based on a quality problem, which relates to parts that do not meet customer requirements and would result in late deliveries and increased part cost. The reasons for any tools transfer should be communicated to the new molder at the time of transfer. If, after transfer and review of the problems, the new molder accepts the tool anyway, then provisions should be made to provide the assets to fix the problems. All company departments should be involved in evaluating the transferred tooling before accepting it for production. If, after evaluation, the tool is deemed not capable of producing good parts, the job should be refused.

Once the company’s quality objectives are defined, it is the responsibility of the sales department to solicit new business. It is also the responsibility of the other company departments to support the sales function, guided by management quality objectives, in obtaining the kinds of customers the company wants to cultivate.

Sales must sell the company’s capabilities and its commitment to providing a quality product. There are four basic types of quality agreements a company can provide to meet customer requirements. Because all customers will not
require the same quality for their products, the necessary degree of quality must be known and determined at the start of any new program. This degree of quality should never be lower than the company’s own quality objectives. It will relate only to the quality level of the specific program. In short, the company must always provide the same high overall quality standards, but they should be adapted through job requirements to suit each specific customer product. To vary the company objectives would be to sabotage the whole total quality process control system.

CUSTOMER-SUPPLIER QUALITY AGREEMENTS

Captive Part Quality

The captive part quality method uses the first article out of the tool that the customer judges as acceptable in a form, fit, and function reference. This first article is used to define the minimum quality values acceptable for the part. Thereafter, quality reference is judged against this part with no critical divergence tolerated. Quality is based on the minimum, or low side, of the part, and value judgments are constantly being made against this standard. Color, clarity, no-flash, warpage, etc., may be the only standards the part must pass. This makes value judgments more acceptable by more people but, in disputes, the customer is the final decision maker. This is an example of quality set up for nonfunctioning or mainly high volume, low cost, aesthetic parts in the less expensive plastics. The part is either accepted or rejected with no middle ground. Documentation is minimal and no attempt to improve or evaluate part quality is expected or anticipated. These items are usually one-time use and throwaway items, or of a quality that should it fail are of little concern.

PRODUCT QUALITY DETERMINATION

Parts to Print

Quality by “parts to print” relies on the customer providing specifications that in turn become requirements for the product, on acceptance of a contract, by the supplier. These part drawing specifications become the standard against which the product is judged for acceptance. These specifications were determined by the designer to have the part meet end-use product functions. In many situations, the tolerances specified are for metal parts that do not take into effect the behavior of plastics. The designer may tolerate all dimensions per the drawing metal tolerance reference table that is part of the title block, but it is all wrong.

The part designer needs to know or determine what dimensions are actually required, what tolerance is acceptable, and referring to the Society of the
Plastics Industry, Inc. (SPI), material tolerance chart (Figure 1.3), to specify the part dimension tolerance accordingly. The tool builder and molder must also inject their comments on the design and dimensioning. The mold builder will use appropriate cavity dimensions and tolerances to meet the designer's dimensional requirements. The cavity dimensions are based on the material selected, the designer part dimensions specified, the estimated number of mold cavities to achieve dimensions, and the location and number of the cavity gate(s), the opening size, and the balanced cavity and runner system that feeds the part cavity. This is shown in Figure 3.2 for a balanced, unbalanced and family mold cavity layout. When the cavity pressures are not equal, some cavities will be overpacked and others will be underpacked, depending on the timing of the molding machines operations. The goal is to have all gates freeze off at the same time or within a second of each other. If not, the product may not meet the requirements of the designer, even though it may still function as required. Decisions on product tolerances, number of cavities in the mold, and other mold requirements must be made now, not later after the mold is built and production has started.

**FIGURE 3.2.** Mold cavity layout.
Quality by part to print requires that procedures and/or instructions are developed and followed for the manufacture of the product based on the stated specifications. These instructions specify exactly what is required of the product, as well as the tolerances, and dimensions critical to the function of the part. This must be known so the mold can be designed to meet the part requirements. The tighter the specifications, the fewer the number of mold cavities permitted and the more critical are the mold tolerances, gate size, location, and the runner feed system. This also includes the cooling requirements for dimensional control, material type, and even the material source in some situations.

It is very difficult for an injection molder to hold metal manufacturing tolerances on a plastic part. At best, one or two specific tolerances can be held to metal-like tolerances. Plastic materials that are reinforced and/or filled can be held to tighter, like metal, tolerances because of the addition of filler and reinforcing mediums (see Figure 3.3 for a microscopic view of the fibers). Fillers and reinforcement cause lower in-mold shrinkage of the matrix resin because they take up a respective amount of resin volume. In filled resins, the filler material does not chemically or physically attach itself to the base resin, acting only as an inert filler adding a higher degree of stiffness to the part but lower elongation and toughness. The reinforced material is chemically and physically attached to the fibers, and it binds itself to the resin and increases the part’s physical properties. The reinforced materials (e.g., short or long glass fibers) will also experience differential shrinkage because the fibers line

![Figure 3.3](image)

**FIGURE 3.3.** Scanning electron micrograph of impact fractured surface (a) 35% filled material, not reinforced; (b) 35% filled; glass-fiber-reinforced (Ref. [1]).
up in the flow and fill direction. This causes more shrinkage in the transverse
versus the flow direction. Mineral- and fiber-filled materials will experience
less of the flow versus transverse dimensional flow problem, which will result
in less dimensional variance in the part with more uniform overall part
shrinkage.

The molder will also need to know whether regrind is allowed in the part.
Typically, 25 percent or less will not appreciably affect the performance and
processing of the product. But, some resins can be degraded by successive melt
histories through the molding machine that decrease the materials’ viscosity
and impact resistance by breaking down the molecular chains in the resin.
Regrind, rejected parts, runner, and sprue, ground up and fed back into the
hopper with virgin resin, is used to keep material and part cost down. But,
with increasing successive regrind cycles, heat histories reduce the physical
and dimensional properties of the base resin. If a capability study, Cp, is being
run, observe the data and determine whether a noticeable change is found as
the regrind is continually fed back into the system. If a change is noted, then
stop the use of existing regrind and purge it from the system. Then, begin
collecting parts for new regrind as before, and when enough is available, begin
mixing it into the virgin resin as before. Also, if allowed, be sure the regrind
is kept dry as hot polymers have an affinity for moisture pickup. Regrind
should be used as soon as possible and fed back into the hopper dryer system
in the correct proportions of 25/75, regrind to virgin resin. Therefore, the use
of regrind must be discussed before a pricing and specification decision is
made for the product.

Custom injection molders are very accommodating in trying to meet their
customers’ “reasonable” part tolerances. They are often aware of part quality
standards regarding part tolerances. Lower requirement part types, such con-
csumable products, dunnage items, throw away after one use parts, meter
closure tags, spacers, and covers, can provide a valuable service and savings
to their customers. For these parts, tolerances are often said to be “open”
meaning not critical. What may be critical is that no flash occurs on the parting
lines, color is controled, that the snap and press fits the work, the information
on the part is readable, and that part properties meet end-use requirements,
such as cable ties, clips, and so on.

What customers may find more important are the following items: the
product diameter, round not elliptical; no voids in the thick section of the part;
clarity is achieved; no scratches on the part; smooth surface; and no weld lines
or warpage is visible. These are specific and critical items for plastic
products.

FORM, FIT, AND FUNCTION (FFF)

Some parts may have only form, fit, and function requirements as those just
described. These parts have the lowest quality requirements, and the method
of acceptability must be decided between the designer and part supplier, which
uses the injection molder, before signing a contract to furnish the product. The main consideration is whether the part can be manufactured as designed and in the specified material with the part tolerances and requirements presented to meet FFF and at the price estimated to be profitable.

If any of these part tolerance and specification questions cannot be answered, then the program should be reevaluated. The greater the number of mold cavities in a mold, the more latitude must be allowed in the part’s tolerance. Therefore, there are really only two types of plastic part tolerance requirements, as listed on the drawing specifications and FFF.

The important item to remember when discussing the manufacture of a plastic product is whether the tolerances are realistic, attainable, and capable of being produced repeatedly from the tooling (mold) and material as specified for the product? These items are negotiable, and an injection molder should not accept metal-like tolerances on a part drawing. The variance of plastic should be discussed and a compromise reached on exactly what is required for the part dimensions and end-use function.

It is difficult for some injection molders to discuss tolerance, as they often feel this reflects on their ability of manufacture. Molders can use the Society of the Plastics Industry, Inc. (SPI) molding tolerance specification for different plastic resins, as shown for acrylonitrile butadiene styrene (ABS) in Figure 1.3 as a part tolerance capability molding guide. Then when the part is molded in a multicavity mold, the dimensions will be in agreement with the standard and the part will be assembled and can function as required.

**PRODUCT REQUIREMENTS**

Many parts must meet agency, government, military, automotive, electrical, medical, food, and plumbing standard requirements for products in specific consumer and business areas. These agency publications state what standard the part must meet beyond even the drawing specifications. Plastic materials are used in parts that go into almost all of today’s products.

These standards are very specific allowing only specific company-approved and certified materials to be used in an application, medical, electrical, and plumbing that were formulated for a specific standard specification. As a result, the supplier has a responsibility to inform the designer if they are not aware of the standard requirements for their particular application. In like terms, only specific materials are listed as approved materials for like applications, especially many automotive parts.

**EXISTING MOLD CONSIDERATIONS**

When a customer wants the injection molder to take over an existing mold from either their operation or another supplier, several areas must be explored.
The first is, why is the mold being moved? There can be several reasons why the mold is being moved, such as follows:

- Machine size not available for running mold
- Obtained a better part price with a requote
- No time or machine to run mold internally
- In-house or outside molder was not able to make good parts
- Molder wanted mold removed from their plant
- Mold was poorly designed and manufactured, last resort trial

It is important to know why an existing mold is being moved or requoted. Was there a problem with the mold? Were good parts ever made from this mold? A whole list of questions can be asked to obtain the information on why the mold is being requoted. It is important to evaluate an existing mold for its capability to produce acceptable products.

Custom molders are often asked to quote existing molds. Never accept a new job with an existing mold without first evaluating it or, at the least, talking with the last person to run the mold, if possible. The mold should be evaluated with a molding trial to produce an acceptable part for verification of the mold and materials quality and moldability. Unfortunately, not every mold built can make acceptable parts. The mold should be evaluated for operation, temperature control, balanced cavity layout, material flow/gate size, freeze off time, and capability of maintaining uniform part weight, cavity to cavity.

I have seen a brand new mold built with the cooling channels 4 inches from the cavity surface. The acceptable steel thickness to the inside channel surface would have been 0.375 inches for this single-cavity mold. This result is totally unacceptable as supplied by the lowest bidder! See the mold section for the correct spacing and layout of cooling or heating channels for a mold.

A mold trial will also determine the capability of the mold to produce parts on a uniform cycle and will establish the molding cycle for quote purposes. If a trial is refused, you did not want the program at all, because it possibly has too many problems.

A typical intercompany flowchart for developing the requirements for a new mold to produce an acceptable part is shown in Figure 3.4. Development begins after the order is received and the part is designed. With the material selected, the following operations occur with sizing the mold cavity for material shrinkage plus determining the requirements, which include gate size, material flow in the mold cavity, number of mold cavities, cooling for dimensional control, and other mold and part design considerations before moving on to processing. See the checklists in Appendix C, specifically Mold Design Checklists, number 15 and 16, for the questions needing answered for the building of the mold. Once the mold is completed, the process control variables are established by trying out the mold. Once completed, any minor mold modifications can be made in preparation for production.
MANAGING FOR SUCCESS, COMMITMENT TO QUALITY

ESTABLISHMENT OF RESPONSIBILITY

Producing plastic products by injection molding is the responsibility of the entire organization. Referring back to Figure 3.1, the flow of responsibility for the product and its quality passes through the entire organization, from sales to shipping and back to sales, for follow-up and maintaining customer satisfaction.

Each department and company manager has their specific input for the quality and process control of the product. Each manager must perform their tasks as required for the product to traverse through the organization to achieve product realization. Their actions and responsibilities are shown in Figure 3.5 for a typical company departmental organization and responsibilities for operations. To ensure all operations are completed, checklists are recommended.

Checklists should be used to ensure all the information is available for their department’s operations. The checklist should list all the duties that are to be performed in the department, even though all may not be done each time an order is received. It is easier to bypass a requirement, if not needed, than to try and remember it each time an order is received. Therefore, a list of the major items each department may perform is listed as a guide for implementing the checklists.
1. Sales: contacts customer, gather information and needs, gets order
2. Contracts: obtains order, negotiates, for product with price established
3. Development: establishes and finalizes part requirements
4. Design: designs product to meet end-use requirements of customer
5. Specifications: customer and design input to establish part tolerances
6. Plan for Manufacture: determine method of manufacture and operations
7. Purchasing: order material, support items, and select vendors
8. Tooling: design, build, and tolerance mold to meet specifications
9. Production: select injection molding machine and auxiliary support equipment
10. Process Control: establish manufacture control points and tolerances
11. Inspection: verify control of process and parts meet specifications
12. Test: perform end-use tests on parts to ensure requirements are met
13. Assembly: may occur before test, ensure parts are assembled correctly
14. Decorate: added value to product if required, information on part
15. Ship: pack product for shipment as required for customer
16. Sales and Service: follow up with customer maintenance and service

This is essentially the process and flow of departmental major actions needed to proceed through the organization for a new order.

DEPARTMENT TQPC RESPONSIBILITY

Based on the task guide presented, it is important that each department participates in the responsibility of the product’s development. Each must do their share of the work for the program to be successful. This implies the use of checklists, procedures, and a repetitive and/or specified method for doing their job to ensure no item is left undone or forgotten.

In a typical custom injection molder, there may be only one employee to cover several departments and operations, which is a stronger case for the use of checklists. The benefit from this is that the employees are more knowledgeable in more areas than an employee in a tightly controlled department in a larger company. Know more, do more, and forget/omit less is the key to this operation.

Often, the supplier is invited to participate in the development of the customer’s product. This gives the supplier a strong area in which their knowledge and experience can affect the performance and quality of the product. By being proactive in working with the customer, they can influence the product’s design, and type of mold, while adding value with the molded-in-part functions to give them advantages over their competition.

Too often in large companies when work is completed by one department and transferred to another, the objective of the product and what was done
earlier to facilitate quality or savings may get lost in the transfer. This is why at the start of a program, the product’s end-use objectives are documented, and all additions to the program are also documented. The manager travels with the documentation to ensure everyone is knowledgeable and the product will meet these objectives.

This product requirement list travels with the documentation, is reviewed by each department involved, and is considered for improvements at each step of the development process. As each item is met, it can be crossed off as completed. Should new ideas influence the product’s development, which includes manufacture, tooling, injection molding, assembly, and decoration, the item is documented on the product manufacturing documentation. Affected personnel are notified, and the revised item is reviewed for incorporation into the program. If a material change is considered for the product, now is the time to do it, not after the mold cavity is sized. Also, under consideration is the end-use environment the part must endure. All of these and more items must be explored. The Design and Development Checklist number 3 in Appendix C is mandatory to avoid overlooking an important item during the initial design phase.

Program Development

Program development begins with the order or the company entering into negotiations with their customer involving the product. At this time, the use of the checklist, Program Development number 1 in Appendix C, is appropriate. The development checklist will assist the company in gathering the information needed to win the order by meeting the customer’s requirements and needs. As discussions proceed, use the checklist with the customer to gather information by asking the questions on the checklist. Depending on the customer, they may be knowledgeable in plastic design or will rely on your expertise in providing them with information on how to best design and lay out their product. In some situations, your customer may be talking with a material supplier who has offered assistance, in the hope their material will be specified for the product. Working with a material supplier can be helpful as long as each of you are in agreement.

During the design phase, consider adding value to the part by molding in secondary functions. These end-use functions can be clips, snaps, threads, flexing and/or open and shutting panels, and so on. Also, consider assembly methods as using screws, press/snap fits, thermal welding, and so on, and decoration as color, molded in instructions on the part, use of decals, metalizing, and other methods. There are separate checklists for these items. The only consideration is to not weaken the part by incorporating these add-on benefits. Be aware that some color systems can lower the physical properties of some materials, plus sharp corners cause high stress concentrations, whereas the use of ribbing and section cutouts can reduce part section thickness and material usage, which conserves material and cost. Listen to the best options of your
suppliers and designers and select the best for your program. The next step is to estimate a piece part price for the product.

ESTIMATED PIECE PART PRICE

Determining the parts estimated piece part cost is usually the next step, with material and molding cycle estimates made to price out the part. This usually occurs after the parts section thickness is determined and ribbing is considered to improve stiffness and strength with the use of molded-in ribs and other part design considerations. An example of a multifunctional symmetrical part is shown in Figure 3.6 with molded-in ribs, cams, bearing, gear teeth, shaft drive slot, and springs.

To finalize part design, a material is selected so the strength of material calculations can be completed. Materials in the amorphous family of plastics have lower physical strength properties than the engineering plastics. They are also less expensive but require thicker sections to carry the same amount of load as the engineering materials. But, by adding ribs on a part, they can be property and price competitive. Therefore, once the design is fairly well along, material selection begins and price estimating can be used to evaluate design, material, and pricing for different materials for the product.

Typically, if the part is straightforward, not complicated by additional part ribbing requirements, press/snap fits, under cuts, ratchets, etc., the material part volume is calculated and you proceed to estimating the finished price of

![Figure 3.6. Multipart functions in a molded part.](image)
the part. If not, then the two different part volumes are determined, molding cycles are estimated on section thickness and known molding variable differences, and pricing continues.

The Piece Part Price Estimating form number 8 is located in Appendix C. You will have to contact the material supplier to obtain its values for section thickness and material setup times, as well as any other information required. The estimating form is discussed in a detailed example for the part, material, and processing variables in Chapter 6.

In analysis, a thinner and physically stronger engineering material (nylon, acetal, etc.) with a faster setup time, even with a more expensive material price per pound, may be more economical. This will be determined during the design pricing study. Material selection may be determined by both physical and/or processing properties. The manufacturing cycle may be the deciding factor by being able to produce more parts using a faster cycle time, which results in a lower part price. This is one consideration the injection molder has to make when quoting a program.

A guide for determining the minimum cycle time while obtaining the necessary part dimensions and tolerances is by molding to the maximum part weight. This is achieved by lengthening the ram forward time on the mold runner system until the part weight is maximized. Once the part weight stabilizes, the hold time for maximum part weight is achieved. This method of establishing the minimum cycle time ensures the part cavity gate is always frozen off before the screw is retracted and builds up material for the next shot. At this minimum ram forward time, no more material can get in the cavity, and it will not depressurize on release of packing pressure and cause a dimension problem.

Also, when determining part cost, the number of mold cavities in the mold is an important factor. The greater the number of mold cavities, the lower the part cost, but the less control of part dimensions results. Therefore, there is a trade-off between part cost and quality requirements when the mold is designed and the cycle times are determined. The piece part cost estimate can be run every time a change is made in the mold design analysis. Once the mold and cycle time are optimized, any assembly operations are considered along with decoration, color, and/or information on the part.

Each plastic material expands during heating and on cooling, and then it returns to its original amorphous or crystalline molecular structure. This requires the mold builder to estimate the amount of mold shrinkage the plastic material will exhibit based on the parts molding conditions, such as melt temperature, cycle times, gate freeze-off time, mold cavity cooling, and part thickness. The thicker sections retain more heat, which causes longer material setup time, and with the engineering materials, greater material shrinkage. Amorphous materials require more heat extraction before they become solid enough to be ejected from the mold cavity so they do not distort. Other mold design considerations will be considered and discussed in greater detail in the mold section of the text.
MULTIFUNCTIONALITY

Plastics have the material capability to perform multifunctional tasks. By selecting the right plastic material, many operations may be accomplished with one part, as illustrated in Figure 3.6. Always consider the plastic part as being multifunctional and evaluate it and the material selected to determine whether it can perform additional functions.

This could cause the individual piece part price to be higher, but it may eliminate other parts, thus reducing the total products cost. This could involve the change of an amorphous material like ABS versus a nylon or acetal engineering material that has physical properties and capabilities exceeding other plastic material. These items are mentioned on the development and design checklists for consideration.

ASSEMBLY AND DECORATING

Plastic parts can be molded with self-locking snap and press fits for assembly with other plastic parts of materials. Permanent assembly is performed with sonic, spin, vibration, and heat welding applications. Assembly with screws, press and snap fits, and clamp methods can ensure repair is possible. Dissimilar materials, with close melting points, within a few degrees, can also be permanently assembled by heat welding methods.

Plastic parts can be colored, painted, printed on, foil and metal coated, dyed, and decorated in a host of many possible ways. Plastic parts are colored for safety reasons, such as to match company products colors, for identification purposes, and any other reason one can think of to color a product. Clear materials are colored as tail lamps and parking lights using acrylic and polycarbonate plastics and others. Basically, it is left up to the part designer to find new and different applications for plastic materials.

MANUFACTURING CAPABILITY

When using TQPC methods for manufacture, control of the program is not left in the hands of a few, but it is the responsibility of many. As described, many employee operations and processes are necessary to get the most value out of a pound of plastic material. The manufacturing department must now have the best possible machines and controls to produce the product within the time schedule and calculated price. Production is responsible for controlling the manufacturing process and for gathering real-time process quality data to ensure the manufacturing process is and remains in control during the entire production operation. The production team must also ensure their
equipment is in good repair, it is clean, it has regular maintenance, the air filters are cleaned or replaced, the controls are calibrated, the machine wear is within limits, and all other items are taken care of to ensure quality manufacture of the product occurs.

The use of checklists and equipment startup instructions should be used to guarantee no items are forgotten and available during this stage of production. It is very important that plant systems and auxiliary equipment can supply their services as needed. Preplanning production startup is important so all the necessary equipment and systems are available for the production run.

The molding machines log book or molding data record sheet (Figure 3.7) is used for recording the startup conditions, ongoing process changes, and final production run settings. This includes all changes to the system before production equilibrium is reached for steady-state operation. Any changes made after this point should be recorded in the molding data record sheet for the run and at scheduled intervals on the system. The exact information should always be recorded; do not use dittos.

Then, as production proceeds, the operator will monitor and document the control settings as necessary at established time intervals while ensuring the process control checkpoints keep the system in control. Should there not be available closed-loop, continuous feedback support, the operator may have to collect data on the process and record the results on a real time run chart. The operator should be trained by quality assurance to perform this monitoring correctly.

**COMPUTER-INTEGRATED MANUFACTURE (CIM)**

Computer-integrated manufacture is used extensively in companies involved in TQPC. It uses the configuration management system (CMS) as its data storage system for the company's manufacturing operations. CIM is a real-time operating/control and information system for controlling and monitoring the business and manufacturing operations of the company in real time. Most CIM systems today record data in real time at manufacturing and monitoring stations, and the data are continually updated and available to management. It can inform specific personnel when event-based “triggers” occur and need attention. This will give any department within the company the actual results of its operations and ongoing order progress. CIM systems track and control orders through the system and out the shipping door to the customer’s dock. In today’s management environment, it is often called “real-time performance management” and can be coupled to “continuous improvement.”

The CIM system can provide the following types of information and services:
**FIGURE 3.7.** Molding data record sheet.
1. Centralized document and record control, protection, and retrieval
2. Control of product and mold design, computer-assisted design (CAD), mold cool, mold flow
3. On-time purchasing and material control for customer part numbers
4. Receiving documentation, inspection, and recording/storage
5. Inventory control of material and equipment usage
6. Maintenance control of all equipments and systems
7. Scheduling of equipment and calibration control
8. Production control and data retrieval and documentation
9. Auxiliary equipment control for production
10. Material control
11. Mold design
12. Finishing and assembly control of products
13. Finished part lot control and storage
14. Packing and shipping control and billing

Plus, there are other software suites that handle other business and molding areas of responsibility. These applications are listed for reference as follows:

- Estimating, pricing, and cycle time calculation
- Tracks production in cycles to handle multicavity molds
- Order processing/invoicing
- Integrated electronic data interchange (EDI)
- Inventory/lot tracking/bin location
- Purchasing [order and bill of material (BM) control]
- Bar code/radio frequency identification (RFID) material and labor control and reporting time
- Purchased material requirements planning finite/infinite scheduling
- Forward/backward—what-if—concurrent
- Schedules machines and molds
- Equipment/machine/mold maintenance
- Program and part pricing
- ISO 9001/TS 16949 quality control standards
- Scrap and regrind tracking
- Assembly and decoration actions
- Work orders and production plans
- CAD
- Calculate mold costs
- Accounting
- Payroll and human resources
TRACKING MANUFACTURE

Bar coding is used to identify products, equipment, material, tools, and so on in a plant and even personnel who perform operations and to monitor equipment usage. Tracking systems can serve multiple purposes, such as follows: recording received items, recording items going through manufacture, locating and indentifying items placed into storage, identifying tools, recording equipment, and tracking personnel performing operations in specific locations. Essentially, any place or item that must be identified, during or after an operation is performed, can be entered into this tracking system as long as a bar code number and label is attached to the item or person’s badge. A bar code label scanner will perform the operation. Inventory control of molding cell equipment usage is essential for scheduling work. Knowing what and where equipment is used and when it will be free is essential information for scheduling production and keeping customer orders flowing and on time.

RFID

A technology introduced in the late 1990s and said to soon replace bar coding is RFID technology. The advantage of an RFID tag on an item is that the target and reader do not have to have an unobstructed line of sight. Because radio waves do not travel in straight lines but reflect off surfaces, they can be bounced around and read, but not necessarily viewed by the reader or person operating the reader used to identify the tag.

We are fairly well versed in the technology because of our garage door openers and car starters from inside the office. RFID is an identification device, not a finding item. It is used to determine “where is my device.”

The RFID system is composed of two basic items, a reader and a transponder, which could range in size from a grain of rice to a hockey puck. The reader sends out a signal that frequency wise is compatible with the transponder, and when queried, it sends back a return signal. The price of the transponder is still a costly issue, but with more large retailers going RFID, such as Wal-Mart, their price will decrease. The real benefit is that an area can be queried and that a return will identify all the tagged items in the area searched. With bar codes, you have to find the item and then scan the bar code to record the item.

RFID technology can identify a series of different products, containers, personnel, machinery, tasks, and so on and can allow data to be collected by employees more accurately, efficiently, and reliably than by any paper-based system. Several RFID standards and technologies are available. Many are proprietary, but a growing number are not.

EDI

Electronic data interchange is a set of standards for structuring information that is electronically exchanged between and within businesses and other
groups using an independent, third-party [value added network (VAN) or e-mail direct using protocols such as file transfer protocol (FTP) or AS2] to receive and then relay the information to the addressee. The standards describe structures that emulate documents, for example, purchase orders to automate purchasing. The term “EDI” is also used to refer to the implementation and operation of systems and processes for creating, transmitting, and receiving EDI documents. Despite being relatively unheralded, in this era of technologies such as the Internet, EDI is still the data format used by most electronic commerce transactions in the world.

**Just-In-Time**

Just in time (JIT) is the manufacturing methods used by many custom and in-house molding organizations. JIT reduces inventory of product, produces parts for orders with sufficient lead time to buy the material, molds the parts, and ships them to the customer in lot sizes to meet the customer requirements. The main requirement is that all items, materials, molds, machines, and personnel are available and ready to produce the product as required. JIT is a precursor to the lean style of manufacture to be discussed later.

The use of these technologies, CIM, JIT, RFID, EDI, and bar coding will uncomplicate, speed up, track, transmit, and locate information and materials before, during, and after operations have been completed. Accuracy will be enhanced along with creating records and documentation of the operations. This will allow more time to be spent in building the business and improving product quality.

**CONTROL OF OPERATIONS**

Operations can be monitored and controlled as described by the five methods discussed: CIM, JIT, RFID, EDI and bar coding. Each has its place in the TQPC system, Tracking orders through design, manufacture, and shipping and keeping a tight schedule for making JIT shipments is a difficult task if the right tools and trained personnel are not in place and performing as required.

Savings of inventory costs have been as great as 50 percent with production improvements of 20 to 30 percent realized through better planning and use of existing equipment and personnel. Just reducing the daily stress in an organization can yield many benefits as the work place is easier to manage. Data are real time information that can be acted on as soon as it is generated. The reduction of errors by just being able to find and know what is available is a major positive change for many companies. The elimination of problems and being proactive in seeking out and performing preventive actions is a major hurdle to overcome.

The correct use of the operating system coupled with a quality system that is proactive and kept current with documentation and records is required for TQPC to perform the functions developed for it. ISO 9001 and its automotive
counterpart ISO/TS 16949 will assist by providing the information and requirements that are necessary for a good operating quality system.

**PROCESS CONTROL**

Process control is often categorized as just monitoring a selected set of manufacturing variables. It is more than this; it is the control of the entire product system. It begins with product design, prototyping, molding, assembly, and all other operations and processes for manufacture by injection molding.

Process control begins with identifying all the product’s variables to ensure that they are identified, considered in their effect on the process, and controlled to produce the product. Variables must be controlled for the entire operation, which include the machine; mold design; material selection; plant, auxiliary, and secondary equipments; mold setup and operating conditions; operator training; and personnel knowledge in injection molding. The latter is often not considered until a key person leaves the company and the design and/or manufacturing program begins to suffer a series of problems related to the prior care and knowledge of the person or personnel who left and took the information with them. This implies that nothing was written down as a part of the daily operation of the manufacturing department and followed for accuracy.

The control and use of documentation and records is vital for all businesses. How these elements are used to understand and interpret information and business and manufacturing knowledge are critical for everyday business operations. Process control is based on using the existing quality control methods in a selected manner to realize the greatest benefit from their application in the business. The recognized quality methods available are shown in Table 3.1. These methods are used for analyzing, monitoring, and improving any type of business and/or manufacturing system. Most of these are recognized as having had their time “in the spotlight” and as having lost the allure, not the confidence of the quality engineer to provide them with the “instant success” they recognize as a reward when using one of the newer quality methods, such as Six Sigma, Lean, and now Lean Six Sigma.

**CONTROL CHARTING**

Data monitoring started with Walter A. Shewhart, the “father of quality” who developed control charts and demonstrated that common cause and special cause variation exists in every system. His use of control charts illustrated how stable or unstable a system was with simple charts and graphs. Many managers today, if asked whether their company’s system is stable, will not have a clue what you are talking about. In fact, most would not have an idea how to use data to demonstrate that stability. At this time, only the methods used to
TABLE 3.1. Quality Improvement Methods.
Quality Methodology Understood:

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<th>Specialist Oriented</th>
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provide process control data are involved in our analysis, the specific type of chart comes later after determining what is to be monitored and by what means. A good source of information located on the Internet is the following website: http://www.isixsigma.com/offsite.asp?A=Fr&Url=http://www.skymark.com/resources/tools/cause.htm, which reviews the different types of quality control charts and quality methods.

Personnel who use and understand control charts often use a sample size of five for data analysis on typical X-bar and R charts. The reason for this is that during the Second World War, the U.S. Department of Defense had to teach untrained personnel to measure the quality of the products they made. The sample size answer was five, because if you take any group of five numbers, add them up, double the sum, and then move the decimal point one place to the left, you will have the average. Shewhart preferred a sample size of four. The same type of reason was used for the time interval for collecting data, every hour, because teaching personnel to calculate a true sampling plan would have distracted them from their output, which was more important.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) ACCREDITATION

Selecting or being required to have your company implement a specific quality-control method (e.g., ISO 9000) or one of the other industry-specific accreditations, to do business with a specific customer, is often required. Certification from specific quality accreditation agencies or meeting a company’s supplier requirement, such as auto company suppliers, who must be accredited to ISO/TS 16949:2002 or higher when revised, is often essential. This implies to the requester that certification will improve or ensure a consistent product quality. In most cases this is correct, but if accreditation is only acquired to become more competitive or a supplier to a company, without management’s follow through for actually meeting and maintaining the requirements, then it is worthless. Unfortunately, this is what happened initially with ISO 9001:1984. Quality was not improved, and in some instances, it was even worse and these companies were still supplying products. This has changed, and the standards are now being adhered to with quality improved as intended.

PROGRAM MONITORING—COMMUNICATION

If you cannot communicate, you cannot successfully operate a business. One of the most important quality functions is learning to listen to your customer. Without quality in communication, a company can lose business share. Poor listeners create a loss of customer confidence by not knowing what their