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Total Quality Process Control

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

Total Quality Process Control for Injection Molding, by M. Joseph Gordon

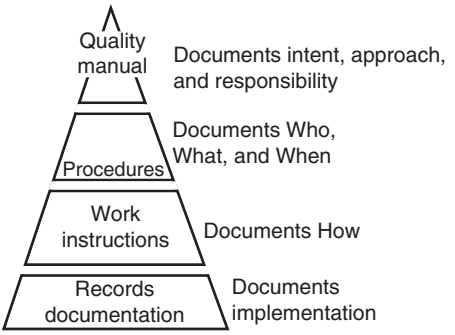


FIGURE 1.1. *The ISO triangle of documentation.*

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 communication 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 documentation as shown in The ISO Triangle of Documentation (Figure 1.1) for ISO 9001:2008. A good quality program, ISO 9001:2008, begins with a quality 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

[1]Smith, L., "The Hidden Cost of Cheap Certification," *Quality Digest* May 2007: 32–35.

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.

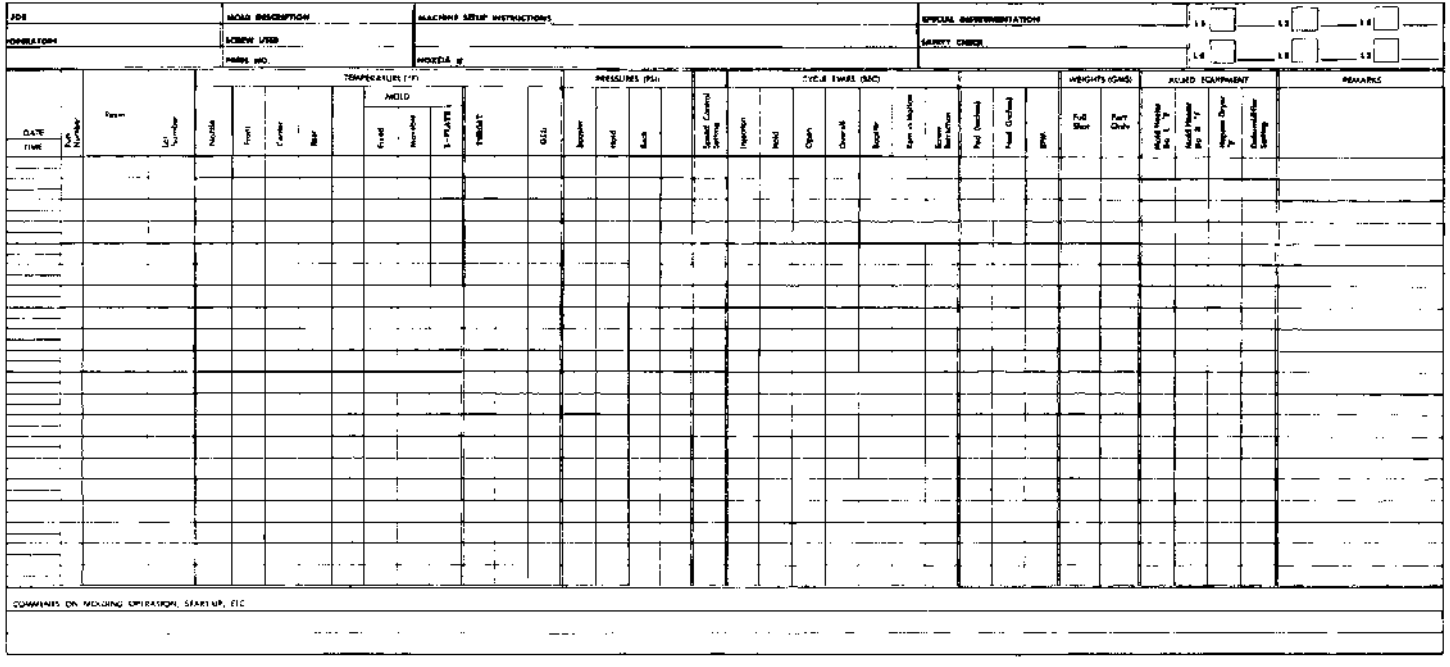


FIGURE 1.2. *Molding data record sheet.*

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[2]

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[2]

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

[2]Harrington, H.S., Performance Improvement "Who Owns the Process?" May 2007: 16.

yourself and employees in the methods and practices of achieving and retaining 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 checklists, 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 essentially 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 definition 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

[3]Six Sigma. Available at: http://en.wikipedia.org/wiki/Six_Sigma.

TABLE 1.1. Quality Improvement Methods.
Quality Methodology Understood:

Program Name	Worker Involvement	Specialist Oriented	Group	Individual	Procedure	Work Methods	Quality	Prod Design	Morale Enhancement	Motivation
Quality Circles	X		X		X	X	X		X	X
Zero Defect	X			X			X			
Employe Suggest	X			X		X	X	X	X	X
Work Simplify	X		X		X	X				X
Qual of Work life	X		X			X	X	X	X	X
Scanion Plan	X		X			X				X
VE/VA		X	X		X			X		
IE Work Study		X		X	X	X				
QA/QC		X		X	X		X			
Org Developmt	X	X	X	X	X				X	X
Fish Bone	X		X	X	X	X	X	X	X	X
SPC	X			X	X		X			X
DOE	X		X	X		X	X	X	X	X
CP/CpK		X		X	X		X		X	X
FMEA		X		X	X	X	X	X	X	
PAP	X		X		X	X	X	X		X
PPAP	X		X		X	X	X	X		X
QFD		X		X	X	X	X		X	X

TABLE 1.1. (*Continued*)
Quality Methodology Understood:

Program Name	Worker Involvement	Specialist Oriented	Group	Individual	Procedure	Work Methods	Quality	Prod Design	Morale Enhancement	Motivation
GMP	X		X		X	X	X		X	X
Kaizen	X	X	X		X		X		X	X
ISO 9000	X	X		X	X	X	X		X	X
TS16949	X	X		X	X	X	X		X	X
CEA	X		X		X	X	X		X	X
8-D	X		X		X	X	X		X	X
Poka-yoke	X		X		X	X	X	X	X	X
VSM (value Stream mapping)	X		X	X	X	X	X		X	X
CTQ	X			X	X		X	X	X	X
VOC	X		X		X		X		X	X
TPS (Toyota)	X	X	X	X	X	X	X	X	X	X
FEA		X		X	X	X	X	X		
TQM	X	X	X		X	X	X	X	X	X
Lean	X		X	X	X	X	X		X	X
JIT	X		X	X	X	X			X	X
5S	X		X	X	X	X	X			X
C&A	X		X	X	X	X	X		X	X
Triz		X	X	X				X		X

- 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:

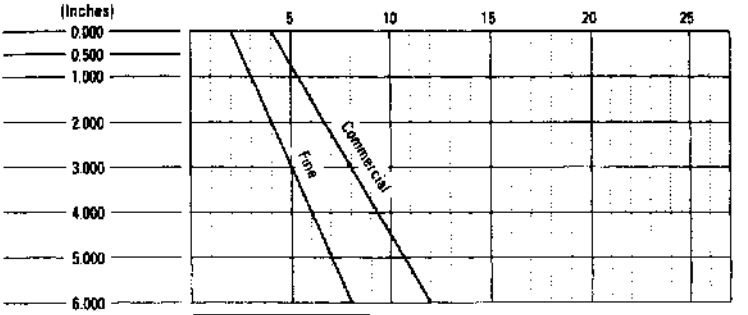
- Selected TQM tools
- Selected BPI tools
- Full-time problem solvers called Black/Green Belts
- Expanded statistical training for a selected group of problem solvers

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

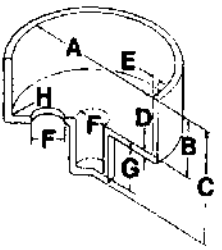
Standards & Practices of Plastics Molders

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.



Drawing Code	Dimensions (Inches)	Comm. ±	Fine ±
A = Diameter (See note #1) B = Depth (See note #3) C = Height (See note #3)	6.000 to 12.000 for each additional inch add (inches)	0.003	0.002
D = Bottom Wall	(See note #3)	0.004	0.002
E = Side Wall	(See note #4)	0.002	0.003
F = Hole Size Diameter (See note #1)	0.000 to 0.125	0.002	0.001
	0.126 to 0.250	0.002	0.001
	0.251 to 0.500	0.003	0.002
	0.501 & over	0.004	0.002
G = Hole Size Depth (See note #5)	0.000 to 0.250	0.003	0.002
	0.251 to 0.5000	0.004	0.002
	0.501–1.000	0.005	0.003
H = Corners, Ribs, Fillets	(See note #6)	0.027	0.017
Flatness	0.000 to 3.000	0.015	0.010
(See note #4)	3.001 to 6.000	0.030	0.020
Thread Size (Class)	Internal	1	2
	External	1	2
Concentricity	(See note #4) (F.I.M.)	0.009	0.005
Draft Allowance per side	(See note #5)	2.0°	1.0°
Surface finish	(See note #7)		
Color Stability	(See note #7)		



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[4] 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

[4]http://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.