

Guidelines for Six Sigma Design Reviews—Part Two

The best way to master design processes is to review them.

by D.H. Stamatis, Ph.D.

Part one of this article, which includes a “Scoring Guidelines” table, can be found on page 27 of the April issue of Quality Digest. It is also on the Web at www.qualitydigest.com/apr02/htmlsixsig.html.

Designing product and process

The second stage in the product development process is designing the product and process. The evaluation here is based on a total of 500 points and is divided into several subsections. Each subsection carries its own requirements and its own weight of points.

The first subsection is selecting product or process concept. The requirements are to create or establish alternative product design and manufacturing process concepts, and to derive best alternatives for development. There are six questions, worth 10 points each, that will facilitate the decision and the process. (See Table 5.) The questions are designed to promote an open discussion about “newness” without fear of intimidation or retaliation. The most critical characteristic of the process isn’t the numerical scheme but the ability to differentiate the product or process differences in a manner that’s appropriate to the customer, the organization at large and the regulatory bodies. A minimum score of 35 is expected, but a good score is anything higher than 45.

When selecting the new concept for product, process or both, the engineer must also consider concurrent product and process designs. This is imperative in our modern world, and this stage of product development should address it. The requirements are very simple but very hard to implement. Specifically, we’re interested in design and model products and processes concurrently using low-cost tolerances and inexpensive materials. (We can do that with parameter and tolerance design, as part of the development phase, with the sole purpose of creating robust designs. That’s why, in design for Six Sigma, we must focus on $Y = f[x, n]$ rather than the traditional $Y = f[x]$.)

In this subsection, there are 14 basic questions, worth 10 points each, which will facilitate the decision and the process. The questions are designed to promote an understanding of concurrent engineering and the application ramification in the design process. (See Table 6.) This is the stage in which much engi-

neering discussion is geared toward alternative analysis and optimizing testing possibilities. The important characteristic of this particular review process isn’t the numerical scheme but the ability to express the differences in a manner that’s appropriate to the customer, organization at large and the regulatory bodies. The basis for this analysis is focused, as appropriate, on trade-off and many other tools and methodologies. A minimum score of 85 is expected, and questions five through nine should have a minimum value of eight points each. A good score is anything higher than 115.

The third subsection in evaluating the design product and process is the approach (i.e., methodology or process) that allows the engineer to identify and prevent failure. The requirement here is to improve product and process through reduction of potential failure modes and functional variability. (See Table 7.) Usually in this category, there are four core questions, worth 10 points each, which guide the evaluation process. The numerical scheme isn’t as important as recognizing and discussing potential failures and eliminating them from the design. The questions should facilitate the process and will focus the discussion to priority items. A minimum score of 25 is expected, and question two should have a value of 10 points. A good score is anything higher than 30.

The fourth component in evaluating the design product and process is the optimization function in the presence of noise. In design for Six Sigma, this is the most important characteristic. The DMAIC model focuses on fixing problems, whereas design for Six Sigma focuses on prevention and robustness. Robustness is indeed the design’s focal point if we’re really serious about improvement.

The traditional model of $Y = f(x)$ is no longer appropriate. We must focus on the $Y = f(x, n)$, which means that the customer functionality (Y) must be satisfied with engineering requirements (x) but in the presence of noise (n). Therefore, the requirement at this stage is to optimize product and manufacturing/assembly process functions by testing in the presence of anticipated sources of variation (i.e., noise). There are six questions, worth 10 points each, and they should serve as the springboard of ideas for sound evaluation. (See Table 8.) A minimum score of 35 is expected, and

Table 5: Requirements and Criteria for Selecting the Product or Process Concept

Item #	Criteria	Score
1	Best-In-Class components are evaluated for craftsmanship, cost, weight, material, quality, serviceability and variation and method of manufacture; and competitor's components are accessible (boarded if possible) for reference.	10 max
2	Applicable advanced technology concepts have been researched, evaluated and included (where applicable).	10 max
3	Robustness implications of the advanced technology concepts have been considered; concepts are prioritized by their potential for robustness.	10 max
4	New product and process concepts have been evaluated against customer-driven criteria.	10 max
5	A better concept has been systematically derived by combining the best features of available product and process concepts.	10 max
6	Design conflicts/contradictions and manufacturing feasibility issues have been identified and addressed.	10 max
Section Subtotal (60 points possible)		
Typical working documents for this substage are:		
<ul style="list-style-type: none"> • Concepts brainstorming • Review past/current technology • TRIZ studies • Competitive benchmarking • Parametric attribute analysis/concepts matrix • Preliminary manufacturing feasibility 		

Table 6: Requirements and Criteria for Concurrent Product and Process Design

Item #	Criteria	Score
1	The manufacturing, assembly, inspection (GD&T) and serviceability processes are developed simultaneously with the product design.	10 max
2	Initial design for product and process includes product reusability (components, tools, fasteners and fixtures) and craftsmanship.	10 max
3	The initial design uses low-cost materials and maximum manufacturing/assembly tolerances with the goal of obtaining high quality/reliability at low cost.	10 max
4	Engineering calculations (e.g., physics stress/strength and thermal expansion) have been analyzed for product/process initial design.	10 max
5	Initial product and process design embodies the appropriate "design fors" (design for assembly, design for disassembly, design for manufacturing, design for service, design for reliability, design for reusability and so on).	10 max
6	Verify that the design meets all worldwide design requirements/regulatory/safety/campaign prevention requirements. Relevant critical characteristics have been identified and communicated to manufacturing/assembly and suppliers.	10 max
7	Simultaneously update design verification testing while developing design.	10 max
8	Where appropriate, analytical models (CAE) have been utilized to identify and improve physical and functional performance.	10 max
9	Reliability/quality targets have been estimated and actions taken to improve the product/system performance over time.	10 max
10	Mistake-proofing techniques are utilized as appropriate.	10 max
11	Tests for discovery have been conducted to verify assumptions and confirm engineering theory.	10 max
12	Assessment of function/cost weight/reliability has been conducted for current organizational requirements, its subsidiaries and competitive designs. Design opportunities have been implemented to provide increased value (VA/VE).	10 max
13	Manufacturing/assembly feasibility has been assessed and issues resolved.	10 max
14	A series of constructive peer/expert design reviews have been conducted to improve the product and process.	10 max
Section Subtotal (140 points possible)		
Typical working documents for this substage are:		
<ul style="list-style-type: none"> • CAE/FEA reports • Tests for discovery • Analytical calculations • Peer design reviews • VA/VE reports • Critical characteristics • Craftsmanship guidelines • Manufacturing feasibility report • Poka-Yoke techniques • DVP • Reliability target documentation • "Design for" studies • GD&T study or example 		

Table 7: Requirements and Criteria to Prevent Failure Modes and Decrease Variability

Item #	Criteria	Score
1	Historical failure modes (e.g., warranty, TGW, lessons learned, including campaign prevention) were reviewed and initial design and process failure modes identified by a cross-functional team.	10 max
2	Design and process improvements identified and implemented to reduce occurrence/severity (DFMEA/PFMEA) of functional variability.	10 max
3	Cost and quality effect of reduced functional variability determined.	10 max
4	DVP includes analysis/tests for priority potential failure modes.	10 max
Section Subtotal (40 points possible)		
Typical working documents for this substage are:		
<ul style="list-style-type: none"> • Functional block diagrams • DFMEA/PFMEA with cost and quality effect of actions • Analysis of historic failures • Fault tree analysis • DVP • Campaign prevent documents • Process decision program chart • FMAs 		

questions four and five should have minimum values of nine points each. A good score is anything higher than 45.

The fifth component of designing product and process is the issue of tolerance design—perhaps one of the most misunderstood concepts in any design endeavor. Tolerance design isn't the same as tolerancing; major differences

exist between the two. Tolerance design forces the engineer to think in terms of modern systems—i.e., a holistic, top-to-bottom approach.

The requirement for tolerance design is to adjust product/process tolerances and materials to achieve a desired performance, with cost-benefit trade-offs factored in. Key characteristics for manufacturing

control and continued variability reduction must also be identified. There are four questions, worth 10 points each, which deal with this subsection. (See Table 9.)

The sixth subsection of designing the product or process deals with finalizing process/control plans. The requirement here is to concur with process tooling, gages and control plans. There are nine

Table 8: Requirements and Criteria for Optimizing Function in the Presence of Noise		
Item #	Criteria	Score
1	Product/process experimentation strategy are concurrently developed within (and between) each of the system's functional boundaries.	10 max
2	For each function, the system signal, control, noise factors and response have been identified.	10 max
3	Strategy developed for anticipating effects of major sources of noise during experimentation for each of the system's functional elements.	10 max
4	A series of product and process experiments have been conducted to optimize functional performance in the presence of noise.	10 max
5	DVP includes important noises for priority functions.	10 max
6	Assumptions used in the analysis have been verified and functional/cost performance improvements (for both product and process) are documented.	10 max
Section Subtotal (60 points possible)		
Typical working documents for this substage are:		
• P-diagrams	• Correlation analysis	• Control factor orthogonal array
• Identify signal, noise and control factors	• DVP	• Regression analysis
• Identification of responses	• Design of experiments	• Confirmation experiments

Table 9: Requirements and Criteria for Tolerance Design		
Item #	Criteria	Score
1	Cause and effect relationships between material/tolerance choices and functional performance have been systematically studied (using designed experiments) and understood.	10 max
2	Design has been modified to selectively adjust product and process tolerances and materials to meet functional targets.	10 max
3	Tolerance studies (e.g., root mean square, worst case stack-up, GD&T, etc.) are finalized for fit and finish to matching components.	10 max
4	Potential significant characteristics have been identified and communicated to manufacturing/assembly where further variance reduction (within the tolerance range) will improve functional performance and customer satisfaction.	10 max
Section Subtotal (40 points possible)		
Typical working documents for this substage are:		
• Interrelationship diagrams	• SC identification evidence	• Revised engineering specification
• Tolerance design studies	• DOE results showing significant tolerances	• Percentage contribution to variation in function
• Cause and effect diagrams	• Drawing showing SCs	

Table 10: Requirements and Criteria for Finalizing Process/Control Plans		
Item #	Criteria	Score
1	Key product and process characteristics translated to process control plans.	10 max
2	Key measurement processes are identified, specified and reviewed.	10 max
3	All DFMEA/PFMEA high risk failure modes have mistake-proof methods designed into the respective product and/or process.	10 max
4	Manufacturing process sheets, operator instruction sheets, and job aids have been reviewed. (This is very important for assembly plants and suppliers.)	10 max
5	Training plans for engineers, operators and skilled trades are reviewed.	10 max
6	Preventive, predictive, and general assembly/manufacturing/supplier repair/rework plans and procedures reviewed.	10 max
7	Process and gage control plans are reviewed (including recalibration schedules and reaction plans for out-of-control).	10 max
8	Supplier FMEAs and control plans have been reviewed by the appropriate engineering activities.	10 max
9	Linkage between DFMEA, PFMEA, DVP and process control plans is evident.	10 max
Section Subtotal (90 points possible)		
Typical working documents for this substage are:		
• Process control plan	• Operator/skilled training plan	• Updated DFMEA/PFMEAs with mistake proofing
• Process sheets	• Process/gage control plans	• Repair/rework procedures
• Example of illustration sheets/job aids	• Maintenance procedures	

questions that should guide the evaluation process, worth 10 points each. (See Table 10.) A minimum score of 60 is expected. Question three must have a value of 10 points, and questions five through nine should each have a minimum value of nine points. A good score is anything higher than 75.

The seventh subsection of designing the product or process is design verification. The requirement for this substage is to integrate and verify design and manufacturing process functions with production-like hardware and/or software. There are seven questions, worth 10 points each, which may facilitate the understanding and decision making. (See Table 11.) A minimum score of 40 is expected, and a good score is anything higher than 55.

The third stage in the product development process is to verify product and process. The evaluation here is based on a total of 100 points and is divided into two subsections. Each carries its own requirements and weight of points.

The first subsection deals with design/manufacturing confirmation. The requirement here is to confirm manufacturing and assembly process capability to achieve design intent. Remember that the intent is always driven by the customer's functionality. Therefore, if the intent is not met, functionality is not met; moreover, the customer isn't satisfied. There are six questions, worth 10 points each, which focus on this intent. (See Table 12.) A minimum score of 35 is expected, and question three must have a value of 10 points. A good score is anything higher than 45.

The second subsection of verifying product and process deals with launch and mass production confirmation. Obvi-

Scoring Summary Sheet				
Program:	PMT No:	Phone:	Functional Area:	Relevant Milestone:
PMT Name:	Leader:	Date:		
QSA-PD Section	Total # of criteria	Maximum available points	Actual average team score	Comments
I. Define Product and Process		250		
Establish/prioritize customer wants, needs, delights	10			
Derive customer-driven specifications	10			
Define system architecture and function	10			
II. Design Product and Process		500		
Select product and process concept	6			
Concurrent product and process design	14			
Prevent failure modes and decrease variability	4			
Optimize function in the presence of noise	6			
Tolerance design	4			
Finalize product and process plans	9			
Design verification	7			
III. Verify Product and Process		100		
Design/manufacturing confirmation	6			
Launch/mass production confirmation	4			
IV. Manage Program		150		
Form a team	9			
Establish a program information center	4			
Update corporate memory	2			
Total Average Score				

Table 11: Requirements and Criteria for Design Verification

Item #	Criteria	Score
1	Prototypes are manufactured by the production source with production-like content and manufacturing/assembly processes.	10 max
2	Initiate DVP tests and verify that optimized product and process functional performance has met reliability targets under laboratory and/or field conditions.	10 max
3	Review dunnage, packaging, shipping and delivery systems together with testing of dunnage.	10 max
4	Verify service requirements and repair procedures/time studies.	10 max
5	Review manufacturing process and machine capacity/capability verification from vendor sites.	10 max
6	Supplier DVP reports have been reviewed by the appropriate engineering activity.	10 max
7	Concern resolution process is in place, and all relevant activities are identified and tracked.	10 max
Section Subtotal (70 points possible)		

Typical working documents for this substage are:

- | | | |
|---------------------------|--|---|
| • Updated DVP and reports | • Dunnage, packaging, shipping report | • Service procedures/time studies |
| • Test parts list | • Report on supplier readiness for build | • Prototype supplier list |
| • Engineering test plan | • Program risk assessment | • Machining capacity and capability studies |

ously, if your organization doesn't deal with this, it's not appropriate for evaluation purposes. However, if this subsection is relevant to your organization, remember that the requirement here is to launch the product, then ramp up and confirm that mass production delivers function, cost, quality and performance objectives. To

facilitate this, there are four questions worth 10 points each. (See Table 13.) A minimum score of 25 is expected. A good score is anything higher than 30.

Managing the program

The fourth and final stage in the product development process is to man-

age the program. The evaluation here is based on a total of 150 points and is divided into three subsections, each carrying its own requirements and weight of points.

The first subsection requirement is to establish and maintain a highly effective team, for both product and process, that

Table 12: Requirements and Criteria for Design/Manufacturing Confirmation

Item #	Criteria	Score
1	Product engineering supports all prejob No.1 builds and launch with representatives who are knowledgeable of the program and the build/launch procedures.	10 max
2	Review measurement capability and process capability for each significant/critical characteristic using data from manufacturing operations/suppliers.	10 max
3	Review process potential capability/capacity trial data for part submission warrant samples.	10 max
4	Performance to functional specifications verified through "fresh eyes" launch readiness reviews and quantified through validation testing.	10 max
5	Degradation data are used to improve analytical model correlation/test correlation to field performance.	10 max
6	Areas requiring concern resolution are identified, reviewed and updated. PV sign-off is completed.	10 max
Section Subtotal (60 points possible)		
Typical working documents for this substage are:		
<ul style="list-style-type: none"> • APQP documentation • Process capability data from PSW parts • PSW documentation • Work plan of supplier visits • Validation test results • Degradation analysis • Updated PMT risk assessment • S/C & C/C capability • Launch readiness assessment 		

Table 13: Requirements and Criteria for Launch/Mass Production Confirmation

Item #	Criteria	Score
1	Concur with supplier launch support plans.	10 max
2	Support manufacturing, marketing, service and production launch teams.	10 max
3	Review changes in measurement capability, process capability, fit/finish and functional performance resulting from increased volume production.	10 max
4	Strategy developed/refined to produce continual improvement/reduction of product and process variability.	10 max
Section Subtotal (40 points possible)		
Typical working documents for this substage are:		
<ul style="list-style-type: none"> • Launch team member list • Launch team member skills matrix • Process decision program chart • Launch support plan • Concern reaction plan • Supplier capability confirmation • Continuous improvement plan 		

Table 14: Requirements and Criteria for Forming a Team

Item #	Criteria	Score
1	Each multidisciplinary team has established roles and responsibilities.	10 max
2	Team meets on a regular basis and maintains a record of open issues and actions.	10 max
3	The team is fully staffed on time and includes manufacturing, assembly, product engineering, suppliers, customers, etc., with the necessary know-how.	10 max
4	Team member capabilities (skills) have been assessed by team leader. The team has people who are qualified to do the job.	10 max
5	Team member training is provided on a just-in-time basis.	10 max
6	Shared vision/mission statement is fully understood, documented and has the commitment of every team member.	10 max
7	Management fosters team building events/workshops.	10 max
8	Attributes of a high-performance team are evident (i.e., passion for customer, knowledge about the program and corporate requirements, freedom to act without fear, willingness to participate in peer reviews, etc.).	10 max
9	Mechanisms for a learning environment (i.e., dialogue, left-hand column, etc.) are active.	10 max
Section Subtotal (90 points possible)		
Typical working documents for this substage are:		
<ul style="list-style-type: none"> • PMT meeting minutes • Team member roles and responsibilities • PMT roster • Skills matrix for team members • Training plan matrix for team members • Copy of program vision statement • Team-Building activities • Program organization chart • Defined PMT goals • Evidence of learning organizational tools and methods 		

has a shared vision. Without this shared vision, everyone will pull his or her own way, and failure will result. There are nine questions, worth 10 points each, that focus on the team effort. (See Table 14.) A minimum score of 70 is expected. A good score is anything higher than 80.

The second subsection of the fourth stage deals with establishing a program information center. The requirement is to maintain and use this program information center to understand global programs of applicable, social and institutional knowledge. How sad that even major corporations continue to repeat the same steps to a

Table 15: Requirements and Criteria for Establishing a Program Information Center

Item #	Criteria	Score
1	Point-of-need library-like facilities (designated team room/learning center) are established and used.	10 max
2	Program knowledge for product and process (including benchmark competitive information, relevant field data, reliability data, etc.) has been gathered and organized.	10 max
3	Daily operation and management procedures (staff) established.	10 max
4	Corporate lessons learned and best practices have been disseminated.	10 max
Section Subtotal (40 points possible)		

Typical working documents for this substage are:

- Program information center location
- Web site address
- Verbal testimony of "how to use"
- Evidence of use of prior lessons learned
- Roles and responsibilities list for updating knowledge base

Table 16: Requirements and Criteria for Updating Corporate Memory

Item #	Criteria	Score
1	Robustness of product and process improved by application of database information.	10 max
2	Corporate memory system updated with new information/lessons learned resulting from application of appropriate timing activities.	10 max
Section Subtotal (20 points possible)		

Typical working documents for this substage are:

- Updated engineering documents
- Updated lessons learned database
- Global problem solving results in corporate memory
- Robustness studies put into corporate data information base
- Updated timing documentation as a result of team direction
- Updates to design handbook
- Generic FMEA templates updated

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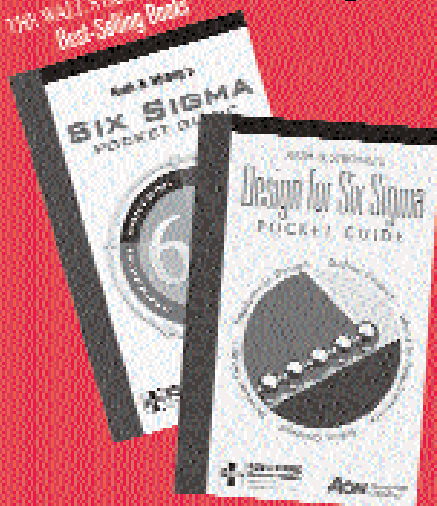
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repetitive problem because no one takes the time to document the information appropriately. In this subsection, we focus on four questions worth 10 points each. (See Table 15.) A minimum score of 30 is expected, and questions three and four must have minimum values of 10 points each. A good score is anything higher than 35.

The third subsection of managing the program deals with updating corporate memory. We all talk about “things learned,” but unfortunately very few of us, if anyone, systematically document these learned things so that they can be used again directly or as a surrogate data for other problems.

The requirement here is to update the corporate knowledge database with technical, institutional and social lessons learned. To do that, the focus is on two basic questions, worth 10 points each. (See Table 16.) A minimum score of 15 is expected, and question two has a minimum value of nine points. A good score is anything higher than 15.

Design review timing

As mentioned earlier, the actual timing is based on organizational and product milestones that are realistic and attainable within the constraints of the organization’s internal and external forces.

It must be emphasized, however, that in any evaluation the three components of approach, deployment and results are kept separately, and vigilance is necessary to keep them under control in each product development cycle. They’re all important.

Summary sheet

For the convenience of the practicing engineer, the summary sheet on page 51 can be used to log the design review process as well as the results.

About the author

D. H. Stamatis, Ph.D., CQE, CMfgE, is president of Contemporary Consultants. He specializes in quality science and is the author of 20 books and many articles about quality. This article is based on his recent work in Six Sigma and Beyond, a seven-volume resource on the subject. More about design for Six Sigma may be found in volume six of that work, which is published by CRC Press. E-mail Stamatis at dstamatis@qualitydigest.com. Letters to the editor about this article can be sent to letters@qualitydigest.com.

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