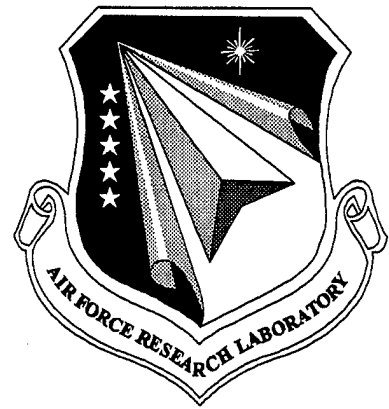


AFRL-ML-WP-TR-1999-4112



MILITARY PRODUCTS FROM COMMERCIAL LINES

VOLUME IA - BUSINESS PRACTICES MANUAL

TRW
Space and Electronics Group
Avionics System Division
One Rancho Carmel
San Diego, California 92128

February 1999

19990723 006

Final Report For the Period 04 May 1994 - 04 September 1998

Approved for Public Release; Distribution is Unlimited.

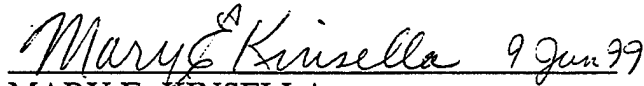
Materials & Manufacturing Directorate
Air Force Research Laboratory
Air Force Materiel Command
Wright-Patterson Air Force Base, Ohio 45433-7734

NOTICE

When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely related Government procurement operation, the United States Government thereby incurs no responsibility nor any obligation whatsoever; and the fact that the government may have formulated, furnished, or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication or otherwise as in any manner licensing the holder or any other person or corporation, or conveying any rights or permission to manufacture, use, or sell any patented invention that may in any way be related thereto.

This report has been reviewed by the Office of Public Affairs (ASC/PA) and is releasable to the National Technical Information Service (NTIS). At NTIS, it will be available to the general public, including foreign nations.

This technical report has been reviewed and is approved for publication.

 9 Jun 79

MARY E. KINSELLA
Project Engineer
Components & Processes Team
Electronics Branch



ROBERT SUSNIK
Chief
Electronics Branch
Manufacturing Technology Division

"If your address has changed, if you wish to be removed from our mailing list, or if the addressee is no longer employed by your organization please notify AFRL/MLME, Bldg. 653, 2977 P St., Suite 6, W-PAFB, OH 45433-7739 to help us maintain a current mailing list."

Copies of this report should not be returned unless return is required by security considerations, contractual obligations, or notice on a specific document.

REPORT DOCUMENTATION PAGE			FORM APPROVED OMB NO. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave Blank)		2. REPORT DATE February 1999	3. REPORT TYPE AND DATES COVERED Final 05/04/94 - 09/04/98	
4. TITLE AND SUBTITLE Military Products from Commercial Lines Volume IA - Business Practices Manual			5. FUNDING NUMBERS C F33615-93-C-4335 PE 78011F PR 3095 TA 01 WU 25	
6. AUTHOR(S)				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) TRW Space and Electronics Group Avionics System Division One Rancho Carmel San Diego, California 92128			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING MONITORING AGENCY NAME(S) AND ADDRESS(ES) Materials & Manufacturing Directorate Air Force Research Laboratory, Air Force Materiel Command Wright-Patterson AFB, OH 45433-7734 POC: Mary E. Kinsella, AFRL/MLME, (937) 255-2461			10. SPONSORING/MONITORING AGENCY REP NUMBER AFRL-ML-WP-TR-1999-4112	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION/AVAILABILITY STATEMENT Approved for Public Release; Distribution is Unlimited.			12b. DISTRIBUTION CODE	
13. ABSTRACT This Business Practices (BP) Manual is the product of the Industrial Base Pilot (IBP) Military Products from Commercial Lines (MPCL) contract awarded by the Air Force Research Laboratory's Manufacturing Technology Division at Wright-Patterson AFB, Ohio. The objective of the manual is to enable the development and manufacture of military products using commercial sources. The Business Practices Manual was developed by an Integrated Support Team (IST) comprised of representatives from defense customers and avionics contractors as well as from commercial suppliers and from national associations. Although developed specifically for electronics, these requirements also useable for any airframes and engines. This document should be used in conjunction with the IBP Model contract to provide a new paradigm for government procurement of military products.				
14. SUBJECT TERMS Business Policies & Practices, RAH-66, F-22, CNI Line Replaceable Modules (LRMs), Manufacturing Infrastructure, Electronics, Communication ECM, Attack & Fighter Aircraft, Manufacturing & Industrial Engineering, Electrical & Electronic Equipment, Navigation Detection & Countermeasures.			15. NUMBER OF PAGES 208	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASS OF THIS PAGE. Unclassified	19. SECURITY CLASS OF ABSTRACT Unclassified	20. LIMITATION ABSTRACT SAR	

Standard Form 298 (Rev 2-89)
Prescribed by ANSI Std Z39-18
298-102

CONTENTS

Foreword	ix
Introduction	xi

Section	Page
BP Manual Section Summary	1
1.0 Management	5
1.1 Cross-functional Teams	5
1.2 Operational Requirements Matrix	7
1.3 Program Control Planning	7
1.4 Benefits	9
2.0 Design Controls	11
2.1 Design Goals	11
2.2 Design Control Model	13
2.3 Design & Development Procedures and Planning	14
2.4 Responsibilities for Design	15
2.5 Design Input	16
2.6 Design Output	18
2.7 Design Reviews	21
2.8 Design Review Terminology	24
2.9 Design Changes and Continuous Design Improvements	26
Attachment A - Operational Requirements Matrix (ORM)	27
Attachment B - Sample Program Control Plan	35
3.0 Parts Control	47
3.1 Parts Control Program and Planning	47
3.2 Supplier's Component Library	49
3.3 Shared Databases	50
3.4 Customer Notification of Product Changes or Phaseout	50
3.5 References	51
Attachment A - Parts Control Program	53

4.0	Configuration Management	67
4.1	Configuration Management Procedures and Planning	67
4.2	Subcontractor Configuration Control	69
4.3	Configuration Control Board	69
4.4	Interface Management	70
4.5	Selection of Configuration Items	70
4.6	Document Numbering Controls	71
4.7	Part Numbering Controls	72
4.8	Configuration Baseline Management	72
4.9	Configuration Change Management	74
4.10	Request for Variance (Waiver/Deviation)	76
4.11	Configuration Status Accounting	76
4.12	Disaster Recovery Planning	76
4.13	Product Serialization	77
4.14	As-built Configuration Record	77
4.15	Configuration Reviews and Audit/Verification	77
4.16	Certification Form	82
4.17	References	83
4.18	Certification Form (Example)	86
5.0	Quality Systems	87
5.1	Risks Influence Government Requirements	87
5.2	Basic Quality System Model	88
5.3	Advanced Best Practices	89
5.4	Quality System Documentation and Planning	90
5.5	Inspection and Planning	90
5.6	Nonconforming Product Determination Authority	93
5.7	Quality Records	94
5.8	Continuous Improvement	95
5.9	Cost-of-Quality	97
5.10	References	98
6.0	Supplier Selection	99

6.1	Source Selection Policies, Procedures and Planning	99
6.2	Source Selection Team	101
6.3	Facility Survey Requirements	102
6.4	Supplier Performance Rating System	102
6.5	References	104
6.6	Subcontractor Self-Evaluation	104
6.7	Attachment A - System Audits	107
6.8	Supplier Relationship Levels	109
7.0	Procurement Controls	113
7.1	Procurement Procedures	113
7.2	Procurement Data	113
7.3	DPAS Priority Rating	114
7.4	Procurement System Evaluation	114
7.5	Attachment A - Procurement Metrics Report	117
8.0	Customer Property Controls	119
8.1	Customer Property Policies, Procedures and Control Plan	120
8.2	Customer Property Management Model	120
8.3	Customer Property Identification, Care and Reporting	122
8.4	Disposal of Customer Property	123
8.5	References	123
8.6	Reference Information Only: Requirements Matrix	123
9.0	Handling, Storage, Packaging and Delivery Control	127
9.1	Handling & Packaging Policies, Procedures and Planning	127
9.2	Packaging	128
9.3	Bar Coding	128
9.4	Handling, Preservation and Protection (ESD)	128
9.5	References	129
10.0	Production Process Control	131
10.1	Process and Control Best Practices	133
10.2	Operational and Process Control Reporting	143
10.3	Demonstration of Operational Controls	144

10.4	Variance Reduction Program	144
10.5	References	145
10.6	Attachment A - Military Specifications Affecting Manufacturing	147
11.0	Product Support and Logistics	149
11.1	Product Support Model	150
11.2	Product Support Plan	151
11.3	Transferable Technical Data Package	152
11.4	Product Support Best Practices	153
11.5	References	154
12.0	Reliability	155
12.1	Reliability Standards and Reference Documents	156
12.2	Reliability Activities and Processes	158
12.3	Reliability Program Goals and Objectives	158
12.4	Reliability Program Model	159
12.5	Reliability Benefits	160
12.6	Customer Reliability Requirements	161
12.7	Supplier Responsibility for Reliability	162
12.8	Product Reliability Program	163
12.9	Failure Reporting	167
12.10	References	169
12.11	Military Reliability & Maintainability Standardization Documents	171
12.12	Software Reliability Overview	175
Appendices		
	Appendix A - Requirements Summary	181
	Appendix B - Key Characteristics	189
	Appendix C - Internet References	193
	Appendix D - Acronyms	197

FOREWORD

This Business Practices (BP) Manual is the product of a the Industrial Base Pilot (IBP) Military Products from Commercial Lines (MPCL) contract awarded by the Air Force Research Laboratory Manufacturing Technology Division, at Wright-Patterson AFB, Ohio. The objective of the manual is to enable the development and manufacture of military products using commercial sources.

The Business Practices Manual was developed by an Integrated Support Team (IST) comprised of representatives from defense customers and avionics contractors as well as from commercial suppliers and from national associations. Although developed specifically for electronics, these requirements should also be useable for any airframes and engines.

This document should be used in conjunction with the IBP Model Contract to provide a new paradigm for Government procurement of military products.

This document is implemented in the spirit of continuous improvement, to provide for facility-wide common processes while eliminating redundant requirements, and providing a winning approach for Government, military contractors and commercial suppliers. The Business Practices Manual enables a win for Government by developing systems faster, cheaper and with better performance and quality. The manual also supports a win for military contractors by providing a new, high quality, low cost sources for military products. Finally, the handbook enables a win for suppliers by allowing commercial suppliers access to military markets.

FOREWORD

This Business Practices (BP) Manual is the product of a the Industrial Base Pilot (IBP) Military Products from Commercial Lines (MPCL) contract awarded by the Air Force Research Laboratory Manufacturing Technology Division, at Wright-Patterson AFB, Ohio. The objective of the manual is to enable the development and manufacture of military products using commercial sources.

The Business Practices Manual was developed by an Integrated Support Team (IST) comprised of representatives from defense customers and avionics contractors as well as from commercial suppliers and from national associations. Although developed specifically for electronics, these requirements should also be useable for any airframes and engines.

This document should be used in conjunction with the IBP Model Contract to provide a new paradigm for Government procurement of military products.

This document is implemented in the spirit of continuous improvement, to provide for facility-wide common processes while eliminating redundant requirements, and providing a winning approach for Government, military contractors and commercial suppliers. The Business Practices Manual enables a win for Government by developing systems faster, cheaper and with better performance and quality. The manual also supports a win for military contractors by providing a new, high quality, low cost sources for military products. Finally, the handbook enables a win for suppliers by allowing commercial suppliers access to military markets.

INTRODUCTION

The Business Practices (BP) Manual is a mechanism to enable a business relationship between a military contractor and a commercial vendor. This document serves to replace military standards and military specifications with requirements based on commercial standards (ISO 9001, QS-9000, etc.) The requirements in this manual define the standards for acceptable supplier practices.

The intent of the BP Manual is to provide the Government or military contractor with sufficient information and guidance to tailor requirements that are mutually acceptable to themselves and commercial suppliers. Developing mutually acceptable requirements is vital in the procurement of a military product from a commercial supplier. With the elimination of military standards and the existence of a wide variety of national standards and competitive industry practices, the BP Manual serves to meet the following objectives.

- Assist the defense industry customer in obtaining a consistent evaluation of supplier's management and process capabilities.
- Convey the defense industry customer's business system requirements to suppliers.
- Assist the supplier in understanding the customer's expectations of the supplier's business systems.
- Identify business system requirements that should be specified in the contract or statement of objectives.

Practices that meet existing standards of the American National Standards Institute (ANSI), International Organization for Standardization (ISO), American Society for Quality Control (ASQC), Society of Automotive Engineers (SAE), Electronic Industry Association (EIA) or the supplier's own competitive commercial best practices may be used to satisfy the intent of the BP Manual requirements. The supplier, however, must have documented processes and procedures and be able to demonstrate compliance with the BP Manual requirements.

The BP Manual establishes a cafeteria-style menu for developing business practice requirements that can be incorporated as part of a contract. Requirements should be kept to the minimum and be tailored based upon the specifics of the product. The supplier may submit alternative approaches, but they must meet the intent of the customer requirements. To work best, requirements should be established in a cross-functional team environment and must be mutually agreed upon by the customer and the supplier.

In addition to the requirements are guidance statements that specify recommended processes. These recommended process statements are not mandatory to the supplier. A recommended process is looked upon as a best practice by the customer and would be evaluated positively during supplier selection if the supplier can demonstrate compliance.

The BP Manual is part of a new process for the procurement of military products from commercial sources. Taken together with the Model Subcontract, the BP Manual provides a framework for the acquisition of commercial items. The following discussion places the BP Manual in the context of the overall DOD Acquisition Reform initiatives.

Acquisition Reform initiatives within the Department of Defense provide a mechanism for procuring military products from commercial suppliers. The key development is the use of a new commercial item definition per FAR 2.101 Definitions and Part 12: Acquisition of Commercial Items. Under this definition, commercial items or ancillary services are defined as:

- (a) Any item that is of a type customarily used for nongovernmental purposes and that is offered and sold competitively to the general public. Commercial items usually have a catalog or published price sheet, are contracted on a firm fixed-price basis and are sold with a product warranty.
- (b) Any item that evolved from paragraph (a) through advances in technology or performance, which will be available in the commercial marketplace.
- (c) Any item in (a) or (b) but for: (1) modifications customarily available in the commercial marketplace or (2) minor modifications to meet the Government requirement. Minor modifications do not significantly alter the commercial function or essential physical characteristic, or change the purpose of a process. Minor may be determined by the modification value, size or scope relative to final product.
- (d) Any combination of (a, b, c, e) that are customarily combined and sold in combination to the general public.
- (e) Installation, maintenance, repair or training services if such services (1) offered to the general public and the Government contemporaneously and under similar terms and conditions. (2) offers to use the same workforce that is used for providing such services to the general public.

FAR Part 12 describes the policy the procuring Agency shall use to make a commercial item determination. *If the commercial item determination concludes that the item under consideration does not meet the definition of a commercial item, the IBP process can not be used. Factors that must be considered include:*

- ability of the product to meet the requirements
- price reasonableness or cost analysis
- quality of the product,
- supplier's past performance.

The Commercial Item determination begins with market research to identify: 1) potential commercial products or services, 2) the quality of these products or services and 3) the level of competition or price reasonableness that exists in the commercial marketplace. The customer must ensure that commercial products meet their requirements for reliability, operational performance and logistics support. Commercial product information, performance data and test data should be used to substantiate market research.

Price reasonableness may be established by comparison to the same or similar items that are commercially available. The supplier may submit information to support commercial pricing, i.e. catalogs or published prices, and their rationale for pricing of modifications.

Contracts for commercial items shall rely on the contractor's existing quality systems as a substitute for Government in-process inspection and testing before the product is tendered for acceptance unless customary market practices include in-process inspection. This manual will be used initially to evaluate the quality system. Specific quality requirements for the procurement will be developed as part of the solicitation process and through negotiations.

Once the item is determined be a commercial item, a solicitation package can be issued to prospective suppliers. The solicitation package should consist of the MPCL Model Contract that includes attached exhibits: a technical data package to include a Performance Specification, the BP Handbook and a Statement of Work. The terms and conditions of the MPCL Model Contract are based on commercial practices and include only three FAR-based clauses:

- Equal Opportunity
- Affirmative Action for Special Disabled and Vietnam era Veterans
- Affirmative Action for Handicapped Workers

The responses to the solicitation package should be used to further qualify the suppliers, serve as a baseline for the eventual contract and establish price reasonableness. The supplier will review the solicitation package from both a contractual and a technical perspective. The technical perspective includes the SOW, performance specification and the BP Manual. The review of the BP Manual includes definitization of the requirements. The supplier review requires a self-assessment of their internal practices using the Operational Requirements Matrix form as a guide. The review may indicate that all operational requirements are adequately addressed, in the

supplier's opinion, by their existing facility-wide processes. In this case, a properly signed certification in the supplier's format is prepared indicating that no further documentation is necessary. If their existing processes do not satisfy all of the requirements, a Program Control Plan must be developed to define what must be changed to address the shortfall.

The supplier will also prepare a Commercial Item Price Evaluation to provide information for evaluating the reasonableness of price. The following topics should be addressed in this position paper:

- Data on sales of the commercial items to the general public.
- Product or process modifications that are customarily available for the commercial product as compared to modifications required for the Government product.
- Specific product and manufacturing process modifications required to meet the Government performance specifications.
- Comparison of the components required for the military product versus those commonly used in their existing commercial products.

Upon receipt of the supplier's proposal, the customer will evaluate the response, select a source and begin negotiations leading to a Commercial Item Subcontract.

BP MANUAL SECTION SUMMARY

MANAGEMENT

Planning for Excellence during a product's life cycle includes requirements definition, design, development & verification, manufacturing, operations and support. These affect all functional groups within an organization and should therefore be developed by the cross-functional teams. Cross-functional teams identify problems early and maintain a cooperative spirit of resolution thereby providing the highest opportunity for program success. Attachment A contains the cafeteria-style Operational Requirements Matrix with recommended requirements for supplier proprietary items, build to print with existing suppliers, build to print with new suppliers and suppliers with design only responsibility. Attachment B contains the Operational Requirements Matrix used for the Industrial Base Pilot requirements and the supplier's Program Control Plan to meet customer requirements that are not addressed by their existing procedures and systems.

DESIGN ENGINEERING

A good design is required to satisfy the customer's performance, price and quality objectives as well as the supplier's profit objectives. The requirements in this section address the process for customer's involvement in the design process.

PARTS CONTROL

A Parts Control Program is an industry best practice for the selection of parts or materials during the product life cycle. The program is established to achieve life cycle cost savings, reduce parts proliferation in a product or system (including reduction of the number of part types, grades or values), minimize the affect of parts obsolescence (out-of-production parts or diminishing manufacturing sources) and improve parts interchangeability, reliability and maintainability.

A Parts Control Program will reduce product cost by knowledgeable selection and control of the component's performance, quality, durability, maintainability and reliability characteristics. The Parts Control section describes the expectations of the customer for control of product and designs and advanced notification when components are being phased out. The supplier may satisfy these requirements according to their internal procedures or a mutually agreed upon Parts Control Plan. An example Microcircuit Parts Control Plan is attached.

CONFIGURATION MANAGEMENT

The configuration management process ensures adherence to customer requirements and product repeatability in manufacturing. Configuration management processes include release controls, implementing changes to design and configuration documents, subcontractor configuration management, disaster recovery planning, as-built reporting and reporting of revision status. Note: This document does not address drawing formats, which must be agreed upon by the design agent and the customer.

QUALITY SYSTEMS

The supplier's Quality System should provide for continuous improvement and variability reduction. The requirements defined in this Business Practices Manual are based on ISO-9001 or ISO-9002. Many industry groups or customers have unique quality system requirements based on ISO-9000: QS-9000 for the automotive industry, D1-9000 Advanced Quality Systems for Boeing and TS-9000 for the telecommunications industry. The Business Practices Manual is our attempt to establish quality system requirements that are acceptable to the defense customer, military contractors and commercial suppliers.

SUPPLIER SELECTION

Source Selection policies and/or procedures address the selection of qualified suppliers, performance rating systems and evaluation of past performance. The technical and cost issues involved with down-selection are not addressed in this document. The Appendices discuss (a) sub-tier supplier self-evaluations, (b) system registration levels and (c) supplier relationships.

PROCUREMENT CONTROLS

Procurement controls are established to provide clear communication of requirements, delivery and acceptance criteria. This section discusses the minimum information necessary for procurement, stresses the importance of the acceptance criteria and discusses the Government priority ratings and allocation system (referred to as DPAS). The Government customer should not require DPAS on a commercial item contract. The Procurement System evaluation (a.k.a. Contractor's Procurement System Review CPSR) requirement is established but a caution is included to make it clear to the Government customer that commercial companies normally do not permit reviews of their procurement system. The commercial suppliers are required to provide evidence of independent or internal procurement system reviews under the ISO requirements. The Appendix contains a typical customer report that might be used in lieu of a procurement system audit.

CUSTOMER PROPERTY

Customer Property controls ensure customers that their property is being properly utilized and protected. The commercial supplier is usually unfamiliar with government requirements for control of customer-furnished property, including identification, care, tracing, and government property reporting, audits and disposal. They usually have the capability to control customer-furnished tooling and material that is consigned by a sub-tier supplier; but material or property which is considered sensitive, including national security, frequently cannot be adequately controlled by commercial companies. The ISO 9001 requirements do not typically require controls for this type of material or property. This is an area where both government customers and commercial suppliers must clearly understand the audit, tracking and reporting requirements and the supplier's capabilities. Tailoring of supplier's procedures in a Program Control Plan is frequently required.

HANDLING, STORAGE AND PACKAGING

Handling, Storage, Packaging and Delivery processes are necessary to avoid product damage during manufacturing or assembly and during shipment and storage. Commercial practices satisfy most cases, but unique customer requirements may require additional instructions for marking of packages, bar coding, or unusual environmental conditions. These instructions are usually found in the Statement of Objectives or contract. This is an area where a clear understanding by both parties is important.

PRODUCTION PROCESS AND CONTROL

Production process controls affect process yield. This section establishes the customer requirements for assurance that these controls are in place and functioning, with particular emphasis on controls and key characteristics.

PRODUCT SUPPORT

Product support covers issues after initial delivery to include replacement, maintenance and product warranty.

RELIABILITY

Reliability or probability that the product will perform in its intended environment for a specified period of time determines the cost for product warranty and the reporting requirements for the customers. This reliability information is used to market the product to potential customers and affects the product warranty and customer's product satisfaction.

1. Management

Objective: To identify problems early and provide the highest opportunity for success.

The supplier shall describe its organizational and technical interfaces, responsibility, and authority with respect to design, parts control, configuration and data management, quality planning, source selection, development and production activities.¹

The requirements developed in this document are only applicable when specified in the Contract or Statement of Work. The following requirements for policies and or procedures are established:

Requirements Summary	Par.
1.	1.1 Cross-functional Teams 1.1
2.	Operational Requirements Matrix 1.2
3.	1.3 Program Control Plan 1.3
4.	1.3.1 Schedule of Key Project Events 1.3.1
5.	1.3.2 Customer Participation 1.3.2

1.1 Cross-functional Teams

Effective planning for excellence during a product life cycle should include a cross-functional team approach to maximize time, money and resources. These teams should be included in requirements definition, design, development and verification, manufacturing and support. Cross-functional teams facilitate open communication links within the company and with customers and key suppliers.

These teams report to a program manager who has overall program responsibility. Cross-functional teams continue to be involved at various stages of development and production and continue throughout the product life-cycle.

These teams are sometimes referred to as "Team Oriented Problem Solving" (TOPS), "Integrated Product Team" (IPT), "multi-disciplinary teams" or "Integrated Product/Process Development" (IPPD).



¹ QS-9000 Quality System Requirements par. 4.1.2 Organizational interfaces,
 QS-9000 Quality System Requirements par. 4.2.3 Use of Cross-functional teams
 ISO 9001-1994 par. 4.1.2.1, 4.4.3

Teams are typically composed of qualified personnel including, as required:

- Customer
- Systems Engineer
- Quality Assurance
- Electrical Engineer
- Configuration & Data Management
- Software Engineer
- Procurement
- Mechanical Engineer
- Key sub-tier suppliers
- Manufacturing Engineer
- Finance or Business Office
- Components Engineer
- Material Control
- Material & Process Engineer

Critical sub-tier suppliers and the customer should also be proactively included as early as possible in these cross-functional teams.

1.1.1 Program Management

The following activities should be considered by the supplier when preparing for a successful project.

- Establish program control plan (see 0) as required
- Determine customer involvement and participation (see 0)
- Determine customer approval for planning documents
- Establish schedule of key project events (see 0)
- Establish a single-point contact
- Provide for customer notification of expected delays or problems

1.1.2 Legal and Ethical Conduct

Proper legal and ethical conduct is a major part of the relationship between customers and suppliers. All suppliers must implement policies and practices that ensure adherence to a high standard of conduct.

1.1.3 Techniques Used for Team Communication

The following techniques for open communication should be employed to the maximum extent possible within integrated product teams.

- Regularly scheduled, frequent IPT meetings
- Informal reviews
- Material status meetings
- Electronic mail
- Common databases

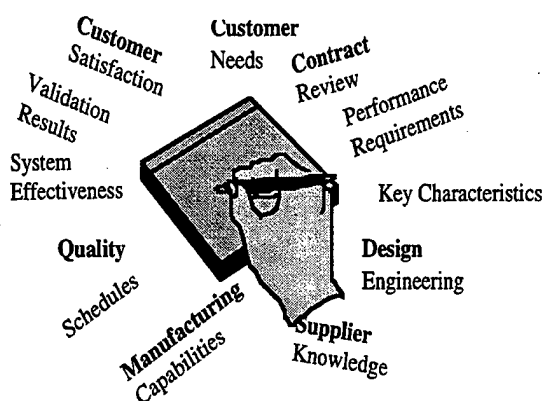
1.2 Operational Requirements Matrix

The Operational Requirements Matrix (ORM) should be used to focus the business practice requirements to the specific solicitation.

The supplier shall return the Operational Requirements Matrix² to evaluate the relationship of the customer's business practice requirements to the supplier's existing quality system procedures, instructions or control plans.

A simple cross-reference of the supplier's procedure to the customer's requirements may be all that is necessary. See Attachment A - Operational Requirements Matrix for the template. Complete instructions for both the customer and supplier are shown on attached ORM form.

1.3 Program Control Planning



When a customer has unique requirements that are not met by the supplier's existing procedures or processes, tailoring of the supplier's processes or procedures is required. This tailoring should be accomplished by program control plans that are specific to this product and will meet the intent of the customer's requirements.

The supplier shall establish, document and maintain a Program Control plan³ as mutually agreed and shall submit for customer review and

acceptance.

The various plans referred to in this document are only required when the customer specifies the plan(s) from Table 1 as a requirement and when the supplier's existing procedures and documentation do not adequately address those requirements. These plans may be combined into one overall "Program Control Plan". Revisions to control plans should be made as requirements or circumstances change during product's life cycle.⁴

Control Plans	BPM Section
Design Control	2
Parts Control	3
Configuration Management	4
Quality Assurance	5
Source Selection	6
Customer Property	8
Handling, Packaging & Storage	9
Manufacturing Process Control	10
Product Support	11

Table 1. Typical Control Plans

² ISO Q9001-1994 par. 4.2.3 Note 8: ... in the form of a reference ...

³ ISO Q9001-1994 par. 4.2.3 Quality Planning

⁴ ISO Q9004-1-1994 par. 5.3.2.3

A certification, in the supplier's format, signed by an authorized company representative, is required for customer review either during the proposal process or as soon as possible after contract award. This certification should include the following.

- how product or processes will be controlled
- roles and responsibilities
- what information/data is collected and how it is used and reported

Attachment B - IBP/MPCL Program Control Plan is included as a typical example of a commercial companies response to the Operational Requirements Matrix. This example shows the case of a Program Control Plan developed for the MPCL project itself.

1.3.1 Schedule of Key Project Events

The Schedule of Key Project Events is used to facilitate communication among the internal and external customers. As a member of the cross-functional team, the customer may wish to actively participate in these events.

The supplier shall establish, document and maintain as necessary, a schedule of key project events⁵ and provide for customer review as soon as possible after contract award.

Key projects for scheduling may include the following.

- Design reviews
- Design Verification⁶ (DV)
- Functional Configuration Audits (FCA)
- Qualification testing
- Design for Assembly or Manufacturability (DFM/A)
- Trial runs or prototype builds
- Production Validation (PV)
- Physical Configuration Audit (PCA)validation or
- Test verifications
- Acceptance inspection or testing
- Incentive fee opportunities

1.3.2 Customer Participation Plan

Customers may require progress reviews during design, manufacturing and product acceptance. These may include witnessing or monitoring inspections or tests required to substantiate product conformance to engineering drawings, specifications, and other contractual requirements. When the customer is an active member in an Integrated Product Team, inspections and tests should

⁵ ISO Q9004-1 par. 8.2.3 Time-phased Design activities

⁶ ISO Q9001-1994 par. 4.2.3f

become more informal or be based on reviews of exceptions. These reviews and tests at the supplier or subcontractor's facilities do not relieve supplier of responsibility for ensuring quality.

The supplier and customer shall mutually establish a Customer Participation Plan for design reviews and verification, and product validation or inspections prior to production release.

The required customer participation will be indicated on the Operational Requirements Matrix or in the contract or Statement of Objectives. Possible participation points are shown in Table 2.

Typical Customer Participation Points.

Typical Customer Participation	BPM Section
System Requirements Review (SRR).....	2
Preliminary Design Review (PDR).....	2
Design Validation (DV/FCA)	2
(Critical Design Review) w/ Functional Configuration Audit	4
Production Validation (PV/PCA).....	4
w/ Physical Configuration Audit	
Customer Surveillance & Inspection	5

Table 2. Typical Customer Participation Points

1.4 Benefits

Customer participation in design reviews, product development and witnessing of production processes facilitates the removal of barriers between the customer and the supplier's internal organizations. The initial startup period from concept to product is frequently increased with the use of an Integrated Product Team. This is a consequence of more thorough up-front planning of the design requirements and production processes. Subsequent production cycle time should be reduced by decreasing the re-design, engineering changes, re-work required and by increasing first pass yields.

2. Design Control

Objective: To provide lowest cost for product development, production, and operation, and the highest level of customer satisfaction.

The purpose of design controls⁷ is to ensure that processes are in place to design products that financially benefit the company and meet customer's requirements and price objectives. Design activities begin at contract award and continue during the product life cycle including product improvements. Design planning should incorporate all functional responsibilities in order to satisfy the customer's requirements and the company's goals and objectives.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix⁸. The supplier's own processes or systems must meet the intent of ISO 9001 and these requirements. The following requirements for policies and/or procedures are established:

Requirement Title	Par.
1. 2.3 Design and Development Procedures and Planning	2.3
2. 2.7.2 System Requirements Review (SRR).....	2.7.2
3. 2.7.3 Preliminary Design Review	2.7.3
4. 2.7.4 Design Verification (DV).....	2.7.4

2.1 Design Goals

Design consists of concurrent design and manufacturing engineering tasks (analysis, simulation, modeling, testing, documentation) required to convert customer requirements into technical specifications, fabrication and assembly drawings, specifications and/or data for a producible product. Design goals may include:

- "Develop quality products that will meet the customer requirements and result in highly satisfied customers."
- "Develop, design, produce and supply products which are most economical, most useful and always satisfactory to the customer" Ishikawa
- "Ability of the product to meet the customer requirements and expectations" Deming
- "Fitness for use" Juran
- "Conformance to requirements" Crosby
- "Design quality into the product" Taguchi

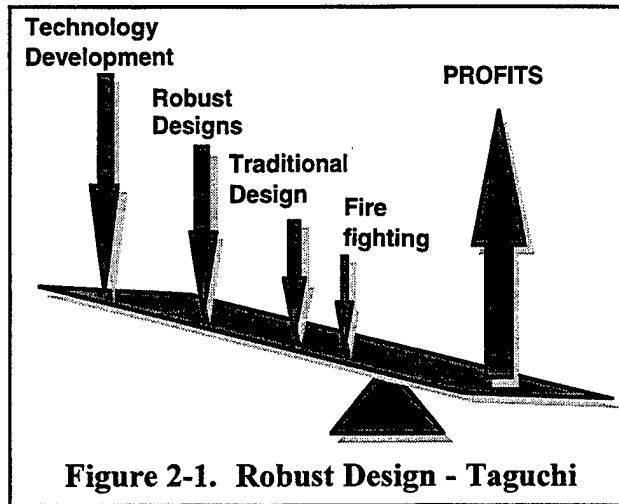
⁷ ISO Q9001-1994 par. 4.4 and ISO Q9004-1-1994 par. 8.0

⁸ Organizational and Technical Interfaces BP Requirements Section 1

The design goals, as defined by the gurus of quality Ishikawa, Deming, Juran, Crosby, and Taguchi may include the following. Design is a critical element of a product's life-cycle, quality and customer satisfaction.

2.1.1 Robust Design

A robust design results in a product or process that produces consistent, high-level performance "despite being subjected to a wide range of changing customer and manufacturing conditions."



Traditional engineering focuses on solving problems, failure analysis, use of a repetitive process of design-build-test, testing one factor at a time, firefighting, and studying in detail problems associated with interactions of the factors involved. This approach costs more, takes more time, and is not always successful. Taguchi's approach allows experiments to be performed and prototypes to be tested on multiple factors at once so that the product or process becomes insensitive to use-conditions and uncontrollable factors.

This is called Robust Design,⁹ and provides a more efficient, cost-effective way to improve products and processes.

- Develop products and processes which perform consistently as intended under a wide range of user's conditions throughout their life cycle (durable and reliable).
- Maximize robustness-improve the intended function of the product by developing and increasing insensitivity to noise factors which tend to degrade performance.
- Develop or change product formulas and process settings to achieve desired performance at the lowest cost and in the shortest time.
- Simplify designs and processes to reduce cost.

The Robust Design process simultaneously yields significantly improved product quality, reliability, and durability while reducing design cycle times and manufacturing costs, and bringing to light new, proprietary knowledge.

2.1.2 Open Architecture

Design architecture defines the structure of interfaces, electrical or mechanical, between the subassemblies that comprise the final product and the external interfaces of the product.

⁹ AMERICAN SUPPLIER INSTITUTE @ <http://www.amsup.com/TAGUCHI/>

The design should facilitate:

- continuous product improvements
- built-in testing such as on-board or in-circuit testing,
- addition of functionality
- modular structure
- adaptable to or interchangeable with other systems, and
- ease of replacement of parts that become obsolete.

Reference: AS 4893, Generic Open Architecture Framework¹⁰ was recently released (1/1/96) by SAE Committee AS-5. "This standard represents the first step in the committee's efforts to develop standards for open systems in support of the changing DoD perspective on military procurement. Generic Open Architecture establishes a hierarchical model that defines nine interface classes, four primary levels, and two secondary levels. It allows for the organization of system requirements and defines how they are applied at the appropriate level to determine interface points. The document provides a framework that identifies the interface classes and is the start point for development of interface standards for system design. It is scaleable in that it can be applied equally well to system or subsystem designs."

2.2 Design Control Model

Figure 2-2. Design Process Model below illustrates a typical overview Design Control process that is timephased during a product life cycle. The dark symbols indicate Design activities or reports that may be required by the customer. The light shaded areas indicate activities that may involve the customer, specifically with cross-functional teams and with respect to the customer reviews that may be conducted. Design reviews are conducted during product definition, development, and production phases of the contract and become major milestones for life cycle phasing.

¹⁰ Society of Automotive Engineers: <http://www.sae.org/NETWORK/openarch.htm>
"Designs should be Flexible, Idiot proof, Simple, and Efficient". Taguchi

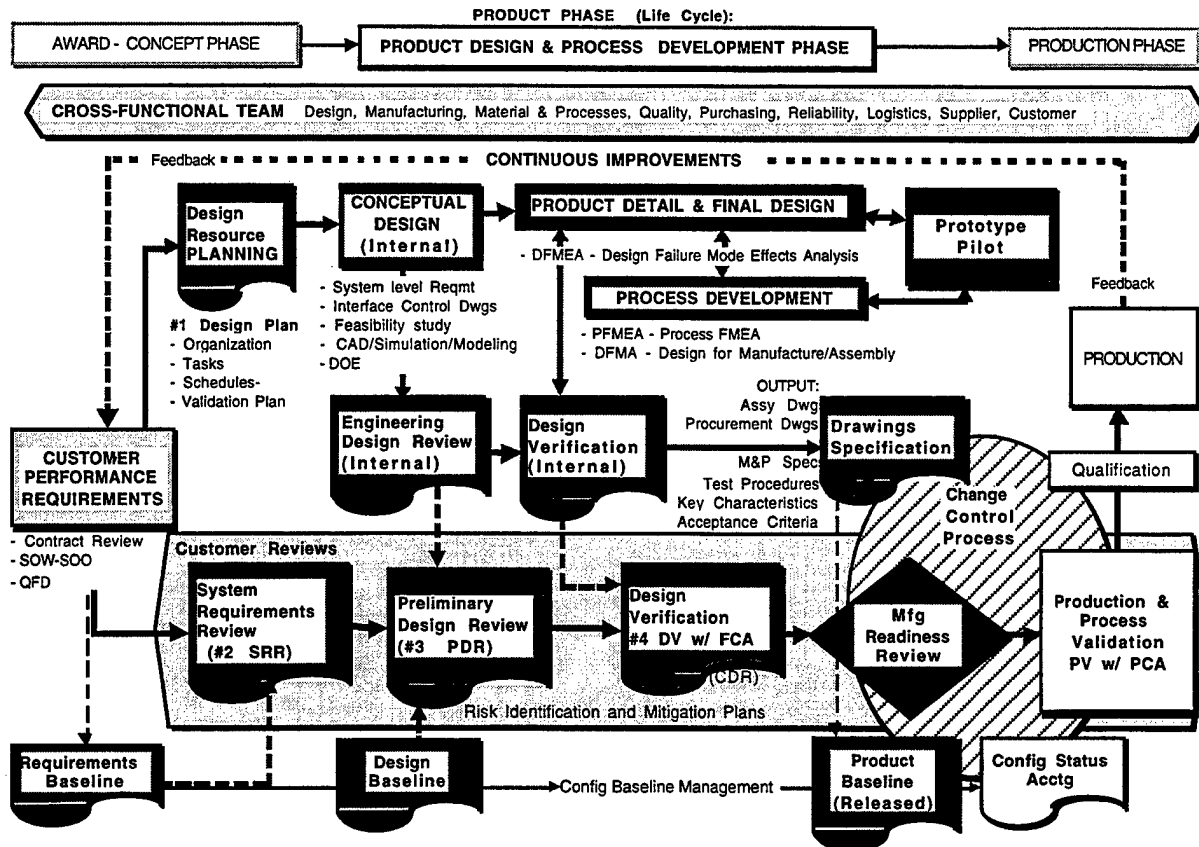


Figure 2-2. Design Process Model

2.3 Design and Development Procedures and Planning

Supplier shall describe its internal design control procedures,¹¹ processes, standards, reviews and product validations which ensure that stated performance and reliability requirements will be satisfied.

2.3.1 Design Control Plan

When the supplier's existing design control procedures and systems do not adequately address a customer's design review requirements, the Design Control Plan will specifically address the supplier's intended approach for obtaining the customer's performance and reliability requirements in the design. The Design Control Plan is required if specified in Section 1.0 Program Control Plan.

The Design Control Plan is developed in sufficient detail by the supplier and provided to the customer to clearly describe the design organization, inputs, outputs, reviews, verifications, validations, schedules, continuous design improvements, and the points at which the customer involvement is available or required. It is recommended that the supplier consider the formation

¹¹ ISO Q9001-1994 par. 4.4.1 documented procedures...

of a cross-functional team¹² to facilitate communication within the company, and to include the customer and key suppliers as early as possible.

2.4 Responsibilities for Design

The following are typical design responsibilities for the design agent.

- Establish customer satisfaction¹³ as a primary design objective and as an element of the supplier's Business Plan.
- Establish budgets (Work Breakdown Structure (WBS), if applicable), and design schedules including allocation of resources available.
- Analyze customer performance requirements and contractual flow down to develop products that make use, as close as possible, of existing equipment and material found in industry.
- Consider Quality Functional Deployment (QFD)¹⁴ (par. 2.5.2) during product design which emphasizes customer's needs and wants, identifies and validates customer's key characteristics, and product support and logistics requirements.
- Establish major component reliability checklist¹⁵ and determine internal and external quality requirements.
- Obtain accelerated supplier delivery commitments, particularly for long-lead items.

2.4.1 Design Approach

The design organization's planning process will address the "best competitive" design approach including investigation of new technologies and state-of-the-art approaches, risk management and mitigation, consideration of trade-off for value, performance, cost, and schedule. After the initial selection of components and products which meet the requirements, on-going parts management participation is necessary to identify alternatives for obsolete or high risk components during product life-cycle.

2.4.2 Source Selection Process

The selection of suppliers¹⁶ who are desirous and capable of providing products and support is critical to the successful design and manufacture of any product. The design team will conduct a competitive market investigation of potential suppliers. The objective of this market research is to observe and obtain, if possible, manufacturer's test results, determine the extent of other

¹² See Section 1.0 Organizational and Technical Interfaces

¹³ ISO Q9004-1-1994 Quality Management and Quality system Elements - Guidelines
par. 5.1.2, 8.4.2a ... Customer's needs and expectations

¹⁴ Quality Function Deployment (QFD) identifies the "Voice of The Customer"; the customer's objectives in addition to the requirements during the early development stages.

¹⁵ Preliminary Major Component Reliability Checklist containing description, supplier, PPM level, incoming inspection requirements, qualification or supplier tests, SQA activity required.

¹⁶ Commercial & NonDevelopmental Items Handbook, 5-1996, Defining Requirements Pg. 20
<http://www.acq.osd.mil/es/std/ndi>

customer usage and product experience, and to obtain independent test lab results, if necessary. See Section 3.0 - Parts Control Program - Parts Selection as an Element of Design

2.4.3 Manufacturing feasibility

To reduce high risk items and potential problems the design team must ensure compatibility¹⁷ of design with production, inspection and test processes and equipment, both internally and at key sub-tier suppliers.

2.4.4 Supplier-identified Key Characteristics

By conducting Design of Experiments (DOE), Failure Mode Effects Analysis (FMEA), or Design for Manufacturing or Assembly (DFM/A) studies, the design and/or manufacturing teams may identify process capabilities or product key characteristics that may affect manufacturing yield which must be addressed in the product design.

2.4.5 Continuous Improvement

The design team should obtain manufacturing process capability, production yield, and field feedback information to improve the design.

2.5 Design Input

Customer performance requirements (Requirements baseline) is the primary driver for the design requirements and are defined in the contract, Statement of Work (SOW), Statement of Objectives (SOO), or Technical Data Package (TDP) provided by customer.

The cross-functional team should ensure that customer requirements are clearly identified and understood by all functional organizations. Statutory and Regulatory requirements (i.e. safety, environmental, etc.) may be thought to be “understood” and may not be defined in the contract, or they may be spelled out by reference to various civil codes, industry standards or, in the case of the Government, by the Federal Acquisition Regulations (FAR). Any differences between customer’s requirements and the supplier’s capabilities need to be resolved immediately. Topics below may not be required or applicable for all product designs or projects.

2.5.1 Contract Review¹⁸

Contract review¹⁹ by members of the cross-functional team is crucial to understanding customer requirements and commitments made by the supplier in their proposal or contract. Review of

¹⁷ ISO Q9001-1994 par. 4.2.3 c ensuring compatibility ...

¹⁸ ISO Q9001-1994 par. 4.3 c ... supplier has capability to meet the contract ...
ISO Q9001-1994 par. 4.4.4 Design Input

¹⁹ ISO Q9001-1994 par. 4.3 Contract Review

the contract and other customer requirements is the primary source for design inputs. These may include:

- customer performance requirements, targets
- specification reviews
- schedules for product, data, incentives, milestone tasks
- supplier developed pre-award (proposal) information
- feasibility analysis: financial, product and process
- verification that design objectives is communicated to cross-functional team.

2.5.2 Quality Functional Deployment

Quality Functional Deployment (QFD)²⁰ is an optional cross-functional requirements definition tool that emphasizes the internal and external customers “needs and wants” during the initial design of the product. QFD provides a method to design-in quality by systematically identifying key product design requirements and resulting manufacturing processes and product parameters. The QFD process will reduce product re-designs, development cycle time, production startup costs, and reduction of future field problems and warranty costs. QFD establishes a relationship matrix between the customer requirements (“whats”), the supplier’s measurable design parameters, and manufacturing planning (“hows”); yielding a better design and more detailed planning. When additional customer “wants” are discovered during this process, the supplier will typically require a revised requirements documents and possibly additional funding to incorporate the “wants.” Using QFD, the customer and supplier will obtain a more defined understanding of the product being developed. It is critical that the process and all subsequent agreements be adequately documented.

2.5.3 Design Rules or Guidelines

The supplier defines the internal procedures and guides to be used during design development, including (a) time-phased design development,²¹ and (b) the conceptual design and development approaches to be used. The development of a Prototype Control Plan is a recommended method for the supplier to assure themselves, prior to production, that the product meets the specifications, that all tests have been performed, that tracking and validating key characteristics are completed, and that all data is recorded as required.

²⁰ Quality Function Deployment (QFD) American supplier Institute, Inc. identifies the “Voice of The Customer”; the customer’s objectives in addition to the requirements during the early development.

²¹ ISO Q9001-1994 par. 4.4.6 Design Reviews
ISO Q9004-1-1994 par. 8.2.3 time-phased design program

2.5.4 Drawings, Specifications and Documentation

All documentation used for product development is required, including standards (National, Military, internal) and sources for technical data or information.

Note: Drawing format is not discussed in this manual. The customer and supplier must agree on these formats. National (ASME Y14.1, ANSI Z1.4-1993) and Military (MIL-STD-100E) standards exist for reference.

2.5.5 Statutory and Regulatory Requirements²²

All Federal, State, and local safety, environmental laws or regulations needed for proper control of environmental emissions and product packaging for transportation are to be addressed in the design plan.

2.5.6 Tools and Techniques

The following are various tools or techniques used for product development.

- Design Failure Mode Effects Analysis (DFMEA) optimizes the relationship between design function, manufacturability, and ease of assembly.²³ DFMEA readily identifies those properties or processes which, based on the suppliers experiences, are considered “special” or “key” to the product’s ability to meet requirements. The DFMEA is an important tool for identification and tracking of the Key characteristics during the design development phase of a project.
- Value Engineering (VE) - cost, performance, schedule trade-off
- Design for Manufacturing or Assembly
- Design of Experiments par. 0.12)
- Process Failure Mode and Effects Analysis (PFMEA)
- Finite Element Analysis (FEA)
- Solid Modeling
- Simulation techniques
- Computer Aided Design (CAD) Computer Aided Engineering (CAE) equipment should be capable of two-way interface with the customer.

2.6 Design Output

The output²⁴ of the design process includes:

- Conceptual designs (par. 2.6.1)

²² ISO Q9004-1-1994 par. 8.2.4

²³ Advanced Product Quality Planning and Control Plan, AIAG, App. B, pg. 82

²⁴ ISO Q9001-1994 par. 4.4.5 Design Output

- Risk identification and mitigation plans (par. 2.6.2)
- Released designs including (a) Drawings and Specifications (par. 2.6.3), and (b) Computer Integrated Manufacturing (CIM) data, as required
- Logistics & Maintenance support requirements (when the supplier has design responsibility that is funded by the customer, a Technical Data Package for re-procurement may be required. See Section 11.0 - Logistics Support for detailed contents).

2.6.1 Conceptual Design

Conceptual design emphasizes establishment of practical, verifiable requirements, and the product architecture, including functional and physical subassembly partitioning. Design decisions made during conceptual design can lock in a high percentage of a product's life cycle costs.²⁵ The conceptual design processes are conducted with internal members of the cross-functional team. Conceptual design reviews are documented, but are less formal than subsequent design audits.

Conceptual designs may include the following elements.

- Feasibility studies (financial, product, or process) are conducted prior to the contract award, when the supplier is submitting their proposal and the general design concept is determined.
- Supplier's design capability determined based on their history, knowledge, experience, resources for technology, type of design being considered, and Computer-Aided Design (CAD) and computer-aided simulation equipment.
- Functional Block Diagram
- Partitioning Hardware and Software
- Interface Diagram
- Technology Insertion ability to meet requirements and emerging technologies that will enhance future upgrades
- Parts and Material selection includes (a) preferred parts lists, (b) reduction of parts obsolescence risks, (c) determination of part maturity, (d) creation of design libraries for parts, failure reporting, customer satisfaction, etc., and (e) part's supplier support availability. See Section 2.0 - Parts Control Program- Attachment A
- Reliability analysis and goals established
- Trade studies
- Electrical design
- Performance simulations
- Design of Experiments: A designed experiment can improve a product's design or the manufacturing processes used in development. The experiments are used to identify

²⁵ Reliability Toolkit: Commercial Practices Edition, Pg. 60 65% of life-cycle costs

manufacturing process parameters or test techniques that affect product performance, producibility and reliability. A design of experiments is a principal method for determining key characteristics to reduce product variation and should be used to increase the product or process tolerances, thereby providing a greater yield. Product application requirements analyzed by members of the cross-functional team determine physical and environmental factors to be tested. A matrix is established to record the results of varying the test parameters. Analysis of these results will then be incorporated into the design or process controls.

- Mechanical design including 3D or solid modeling capabilities which reduces design cycle time and development costs.
- Key characteristics identification and tracking
- Product support, logistics, safety, maintainability issues include (a) designs to facilitate servicing and reduce repair costs, (b) standardization of part's technology, and (c) mechanical design vs. manufacturing capabilities.
- Test plans and procedures define the methods for testing and measurement, allow for Built-in Test with automatic test equipment and establish acceptance criteria for product.
- Producibility assessment accomplished by (a) identification by manufacturing of manufacturing process parameters and controls required to maintain product performance (b) Design for Manufacturability and Assembly (DFM/A) studies, (c) design team's experience, knowledge, history (lessons learned), and technical resources, and (d) by the facilities capacity for technology advances. See Section 10.0 - Manufacturing Systems

2.6.2 Risk Identification and Mitigation

Identifying potential risks and establishing risk mitigation plans should be done during the entire product life cycle (design, production, test, support). Risks may be based on technical approaches, software, program interfaces or availability of processes or qualified personnel. Risks are quantified in terms of cost, schedule, experience or past performance. Risk assessment and mitigation plans are used to rationalize these cost and schedule impacts.

Identify risks, level of acceptability and options or alternatives available to reduce risk, such as:

- Risk avoidance by removal of the requirement
- Risk control by monitoring and using multiple approaches
- Risk assumption by setting aside funds, schedule or performance tolerances
- Identification of part types that may not be available when needed
- Identification of potential software problems
- Risk transfer by insurance, warranty or otherwise passing the repair or replacement responsibility to the suppliers.

2.6.3 Manufacturing Documentation

The final design output consists of all drawings, specifications and procedures needed for manufacturing and or submission to the customer are identified with assigned responsibility for completion.

2.7 Design Reviews

Design reviews,²⁶ an integral part of system engineering, primary purpose are to:

- Determine technical adequacy of the design approach
- Obtain authorization to proceed to the next phase
- Identify and take corrective action for design inadequacies
- Identify potential risks that may arise during design and development and present risk mitigation plans
- Ensure that the design outputs are properly documented.

Design reviews may be conducted or supported by the design agent at various stages from concept through design or production validation. Design reviews include evaluations of all design activities occurring since the previous review and requirements, reliability goals, simulations, results DFMEA, DFM/A, DOE, test failures, and tracking of the design progress. Design reviews become more detailed as the design evolves.

The Program Control Plans, contract, or other appropriate document will document the mutually agreed levels of supplier and customer involvement including as specified: Design Reviews, Design Verifications, Production Validation and a reviews of Final Functional data²⁷. See Section 1.0 - Organizational Interfaces- Customer Participation Plan.

2.7.1 Design Review Participation

Internal design reviews should include appropriate members²⁸ of the cross-functional team and may include the customer and sub-tier suppliers as necessary. Most commercial customers generally do not wish to be involved in design and development process;²⁹ however, some commercial or defense customers may require participation, or at least communication and approval, in the following design reviews.

²⁶ ISO Q9001-1994 par. 4.4.6 Design Review

ISO Q9004-1-1994 par. 8.4

²⁷ ISO Q9001-1994 par. 4.2.3f ... identification of suitable verification at appropriate stages ...

²⁸ ISO Q9001-1994 par. 4.4.6 Design Reviews

²⁹ Benchmarking Commercial Reliability Practices, RAC 1995 Pg. 18

2.7.2 System Requirements Review (SRR)

Definition: System requirements is an internal review during the initial design phase which ensures that all members of the cross-functional team have a clear understanding of the customer's requirements as stated in the contract and related documentation. This review does not usually include customer. The requirement below is added to include the customer participation. The Quality Function Deployment (par. 2.5.2), which requires customer involvement, may be conducted in this review or at a later time.

The design agent shall plan and conduct a formal, documented System Requirements Review³⁰ including customer participation and appropriate personnel representing the functions being reviewed and any other specialized functional personnel as required, and as indicated in the Program Control Plans.

CAUTION: Customer representative participation at the supplier's Systems Requirement Review is NOT a commercial practice and may increase the product costs or preclude contracting with commercial suppliers. If this task is mutually agreed upon, the review should be clearly defined in the contract or statement of objectives and in the supplier's program control plan.

2.7.3 Preliminary Design Review (PDR)

A PDR is a review of the Conceptual Design results. This review may include top-level block diagram, design partitioning, capability assessments, interface requirements, preliminary parts list, technologies to be used, and development of plans for simulation, reliability, maintainability, logistics, and testability.

The Conceptual Design Audit is an internal review by program management and engineering members of the cross-functional team and does not usually include the customer. During the initial engineering validations and feasibility studies, the design capabilities and design approach are evaluated by the internal development team. The requirement below is added to include the customer participation.

The design agent shall plan and conduct a formal, documented Preliminary Design Review including customer participation and appropriate personnel representing the functions being reviewed and any other specialized functional personnel as required, and indicated in the Program Control Plans.

CAUTION: Customer representative participation at the supplier's Preliminary Design Reviews is NOT a commercial practice when the supplier controls the design of the product. Customer participation at the PDR may increase the product cost or may preclude contracting with commercial suppliers. If this task mutually agreed upon, the review should be clearly defined in

³⁰ ISO Q9004-1-1994 par. 8.2 Design Planning & Objectives

the contract or statement of objectives and in the supplier's program control plan.

2.7.4 Design Verification (DV)

A Design Verification,³¹ also may be called a Critical Design Review (CDR), consists of a review of the detailed design results, and a document review process to ensure design documented outputs (drawings and specifications), meet the input requirements prior to drawing release for production. When the supplier is funding the product development customer participation may not be required. However, if the customer is funding the product design and development they are entitled to more involvement in the design decisions and acceptance criteria. The supplier should obtain, prior to beginning production, customer feedback when they do not actively participate in the CDR.

The design agent shall plan and conduct a formal, documented Design Verification Review including customer participation and appropriate personnel representing the functions being reviewed and any other specialized functional personnel as required, and indicated in the Program Control Plans.

Design Verification (DV) typically includes a review of the following.

- Internal design rules
- Comprehensive product characterization
- Sub-assembly definition
- Drawing trees
- Capability assessments
- Alternative calculations
- Trade studies results
- Material definition
- Parts lists
- Comparisons with existing designs or other competitive products
- Test and demonstrations
- Producibility assessments
- Independent verification
- Support engineering requirements

³¹ ISO Q9001-1994 par. 4.4.7 Design Verification
ISO Q9004-1-1994 par. 8.4.3 Design Verification
TRW Automotive - Supplier Development Manual - New Part Launch Pg. III-21, par. 2

- Qualification testing consisting evaluation of performance, durability, safety, reliability and maintainability under storage and operating conditions
- Functional Configuration Audits (FCA) consisting of an examination of pre-production units and test analysis to verify that all design features conform to defined user needs and that the design is capable of being produced (the FCA may also include review of drawings that are deliverable to the customer, for compliance with customer drawing format and content requirements. See Section 4.0 - Configuration Management)

2.7.5 Production Readiness Review (PRR)

A PRR is conducted prior to production, to answer the question “Is everything ready?” and consists of a review of the released design baseline documentation prepared for product development and acceptance. The PRR may include: performance simulations, review of released drawings and specifications, test procedures, acceptance criteria, and a demonstration of producibility. The customer is likely to participate in this review to ensure that their performance requirements are met and that the production processes and program schedules meet their needs. The design agent may be required by the customer to support this review.

2.7.6 Production Validation (PV)

Production Validation³² is conducted by the manufacturer to ensure that the hardware produced is in accordance with released design documentation and will satisfy customer requirements. The cross-functional team, including the design, manufacturing, and customer³³ representatives, perform the Product Validation³⁴ to ensure that the production tooling and processes are producing acceptable products. This review is conducted on the first lot of hardware produced with production tools and processes tested under defined environmental operating conditions.³⁵ This process in defense contracting is referred to as “Physical Configuration Audit (PCA)”.

2.7.7 Design Review Documentation and Certification

Records of all design reviews will be maintained including action items, points of contact, as well as identified deficiencies and corrective actions identified.

See Section 4.0 - Configuration Management - Attachment for sample certification document.

2.8 Design Review Terminology

Table 1. Design Review Terminology relates terms used for different reviews conducted during product development and typical customer participation points. The life Cycle or Configuration Baseline column begins at product concept and continues to the first production unit. The Dual-

³² ISO Q9001-1994 par. 4.4.8 Design Validation

ISO Q9004-1-1994 par. 8.5 Design Qualification and Validation

³³ QS9000 Quality System Requirements (Automotive) Pg. 59 Chrysler-specific requirements

³⁴ Production Part Approval Process, AIAG, Pg. 1

³⁵ Advanced Product Quality Planning, AIAG, Pg. 26 par. 4.5

Use column indicates terminology that is used in this manual. Defense terms were taken from MIL-STD-1521 (canceled April 10, 1995) and MIL-STD-973. Commercial terminology makes use of terms used in the commercial automotive industry.

<u>Life Cycle or Product Phase</u>	<u>DUAL-USE Requirements</u>	<u>Defense Terms³⁶ Mil-Std-973</u>	<u>Comm'l Terminology & Sequence</u>
CONCEPT • Requirement Baseline established	System Requirements Review (SRR) • Supplier IPT ONLY Understanding customer reqmts	SYSTEM REQUIREMENTS REVIEW (SRR) Review may be customer only or may include supplier.	Analytical Design Review Specification Review Contract Review Conceptual Design
PDR • Concept Design Audit • OK- to begin Detail Design • ISO 4.4.6	PRELIMINARY DESIGN REVIEW (PDR) • Supplier IPT ONLY	PRELIMINARY DESIGN REVIEW (PDR) • design progress • technical adequacy • technical risk • interface compatibility	PRELIMINARY DESIGN REVIEW • Initial sample submitted • Engr Design Review • Design Verification DV
DV/CDR • Detail Design Audit - pre Fab • Design Baseline established • Functional Configuration Audit (FCA)	(DV) DESIGN VERIFICATION • Supplier IPT <i>with CUSTOMER</i> FCA review design dwgs vs. reqmts Section 4.0	CRITICAL DESIGN REVIEW • meet customer reqmts • design compatibility • risk areas • producibility • documentation	CRITICAL DESIGN REVIEW <i>with CUSTOMER</i> feedback • Engineering Release Authorization • FCA (If customer-owned design)
Pre-Manufacture • Production Baseline established • ISO 4.4.8	(PRR) PRODUCTION READINESS REVIEW • Supplier IPT <i>with CUSTOMER</i>	Production Readiness Review • FCA • PCA • Formal Qualification Review (w/ FCA)	Manufacturing Readiness Review • <i>CUSTOMER</i> Launch Readiness Review
First Production Units • Physical Configuration Audit (PCA) • First Article	(PV) PRODUCTION VALIDATION • Supplier IPT <i>with CUSTOMER</i> • PCA "As Built" conforms to released technical docs	see above for PCA	PRODUCTION VALIDATION (PV) • PCA • <i>with possible CUSTOMER VISIT</i>

Table 1. Design Review Terminology

³⁶ Systems Engineering Management Guide, Defense Systems Management College, Draft 5/96, Pg. 13-3
References MIL-STD-1521B (now canceled)

2.9 Design Changes and Continuous Design Improvements

The design process is never complete; customer needs continually evolve and all products can be refined to provide current or future customers with a more competitive product by reducing product costs or by increasing product performance or quality, or by offering new or improved products. Feedback from production, testing, or the marketplace (customers) provides valuable information to the design engineers. This information should be collected, monitored, analyzed and made available to designers.³⁷

2.9.1 Design Changes

All Class 1, form, fit, function, interface, design changes³⁸ require documentation and written customer approval or waiver of such approval, prior to production. Section 4.0 - Configuration Management provides a more complete description and requirements for change control relating to design.

For proprietary designs, impact on form, fit, function, performance and/or durability should be determined with the customer so that all effects can be properly evaluated. Customer involvement with the decision to incorporate design changes promotes:

- Funding for added performance capabilities,
- Identification of potential interface affects, and
- Informed consent to incorporate proposed changes impacting system performance.

2.9.2 Continuous Improvement techniques

Typical techniques for continuous improvement may include (a) Capability indices (Cp, Cpk), (b) Design of Experiments, (c) Cost of quality, (d) Parts per million analysis, (e) Value analysis, and (f) Brainstorming.

³⁷ ISO Q9004-1-1994 par. 7.3 Customer feedback

³⁸ ISO Q9001-1994 par. 4.4.9 Design Changes
ISO Q9004-1-1994 par. 8.8 Design Change Control

Attachment A: Operational Requirements Matrix (ORM)

Customer instructions

The customer should use the ORM to determine the requirements based on the type of product, product complexity, and the product's criticality to their system or program. The candidate operational requirements applicable to a specific contract are indicated in the Operational Requirements Matrix "A-B-C-D" columns. The Business Practices³⁹ Manual contains the details and background for each requirement and should be provided to suppliers. The supplier's operational requirements should be determined as early as possible prior to contract award, preferably during the proposal or supplier selection phase.

The requirements matrix should be used to establish a baseline for the procurement as determined by the product complexity, criticality to the project, and by the suppliers previous experience. Any requirement that is not needed for the product or application should not be checked. The requirements should be tailored based on the supplier's status:

- Column A **SUPPLIER PROPRIETARY or CATALOG ITEMS or COMMERCIAL PRODUCTS** - Does not usually require additional controls; all requirements checked are BASIC ISO 9001
- Column B **EXISTING SUPPLIER (Build-to-Print)** w/ good Quality & Delivery history
- Column C **NEW SUPPLIERS (Build-to-Print)** or marginal performance history
- Column D Suppliers with **DESIGN ONLY RESPONSIBILITY**

This matrix should be requested from established suppliers every 1-3 years, dependent upon past performance, to allow revalidation of suppliers.

Check marks in specific cells indicate recommendations of the IBP IST team.

Supplier instructions

When an Operational Requirements Matrix cell is MARKED, the supplier should refer to the Business Practices Manual to understand the requirement in detail. The supplier should reply to the ORM by referencing their procedure which satisfies the requirement.

The completed ORM may indicate that all operational requirements are adequately addressed by existing procedures and processes. In this case, the ORM and a signed certification, in the

³⁹ Recommend Business Practices Manual be available via the Internet, or by accessing a customer's homepage.

supplier's format, indicating that all requirements are met and that no additional documentation will be submitted for customer review.

Program Control Plan

In the event that the supplier self evaluation or a subsequent customer review determines that requirements are not adequately addressed, a Program Control Plan will be requested by the customer. The Program Control Plan addresses supplier shortfalls.

Operational Requirements Matrix Legend

- A = Proprietary, Catalog, or Commercial products
- B = Existing supplier w/good history (Build-to-print)
- C = New Supplier or marginal history (Build-to-print)
- D = Design Agent only (If same supplier is used for Design & Fab, use 2 columns)
- BPM = Business Practices Manual paragraph numbers.
- √ = Recommended baseline determined by customer
- X = Applicable to this requirement, as tailored by the customer

Note: Footnotes in Table below reference the "additional sources" that influenced each requirement.

	A	B	C	D	Source or ISO Par.	BPM Par. No	REQUIREMENTS Supplier shall document, maintain, describe, provide or demonstrate:	Supplier Procedure & Paragraph
1.	√	√	√	√	Q9001-1 Par. 4.1	1.0	MANAGEMENT	
2.			√	√	Q9001-1 Par. 4.1.2 Par. 4.4.3	1.1	CROSS-FUNCTIONAL TEAM/ORG CHARTS	
3.			√	√	Q9001-1 Par. 4.2.3 Note 8	1.2	OPERATIONAL REQUIREMENTS MATRIX customer requirements vs. supplier procedures Completed ORM satisfies requirement	
4.			√	√	Q9001-1 Par. 4.2.3	1.3	PROGRAM CONTROL PLAN	
5.			√	√	Q9004-1 Par. 8.2.3	1.3.1	SCHEDULE OF KEY PROJECT EVENTS Schedule or table format preferred.	

	A	B	C	D	Source or ISO Par.	BPM Par. No	REQUIREMENTS Supplier shall document, maintain, describe, provide or demonstrate:	Supplier Procedure & Paragraph
6.			√	√	Q9001-1 Par. 4.4.6 Par. 4.4.8 Par. 4.4.9 Par. 4.6.4.2 Par. 4.13.2 Par. 4.16	1.3.2	CUSTOMER PARTICIPATION PLAN	
7.				√	Q9001-1 Par. 4.4	2.0	DESIGN CONTROL	
8.				√		2.3	Design and Development Procedures and Planning	
9.				√	Q9001-1 Par. 4.4.2 Par. 4.4.6	2.7.2	System Requirements Review (SRR)	
10				√	Q9001-1 Par. 4.4.2 Par. 4.4.6	2.7.3	Preliminary Design Review (PDR)	
11				√	Q9001-1 Par. 4.4.2 Par. 4.4.6 Best Pract. ⁴⁰	2.7.4	DESIGN VERIFICATION (DV)	
12			√	√	Best Pract. ⁴¹	3.0	PARTS CONTROL PROGRAM	
13	√	√	√	√	Best Pract.	3.1	PARTS CONTROL PROGRAM AND PLANNING	
14	√	√	√	√	Best Pract. ⁴²	3.4	Customer Notification of Product Changes	
15	√	√	√	√	Q9001-1 Par. 4.5 Best Pract. ⁴³	4.0	CONFIGURATION MANAGEMENT	
16	√	√	√	√	Q9001-1 Best Pract. ⁴⁴	4.1	Configuration Management Procedures and Planning	

⁴⁰ TRW Automotive Supplier Development Manual - New Part Launch par. 2 pg. III-21
⁴¹ Boeing Commercial Avionics Systems - Parts Control Program (BD&SG-CAS) D900-10193-1
Ref. MIL-HDBK-965 (9/26/96) Acquisition Practice for Parts Management
⁴² QS-9000 Quality System Requirements, Section II pg. 52, Production Part Approval Process
⁴³ ISO 10007:1995-04-15 par. 5.3, 7.4, 7.7 Configuration Control
⁴⁴ ISO 10007:1995-04-15 par. 5.3, 7.4, 7.7 Configuration Control

	A	B	C	D	Source or ISO Par.	BPM Par. No	REQUIREMENTS Supplier shall document, maintain, describe, provide or demonstrate:	Supplier Procedure & Paragraph
17	✓	✓	✓	✓	Q9001-1 Par. 4.6.2 b) Natl Std ⁴⁵	4.2	SUBCONTRACTOR CONFIGURATION CONTROL	
18		✓	✓	✓	Q9001-1 Par. 4.5.3 Natl Std ⁴⁶	4.3	CONFIGURATION CONTROL BOARD	
19				✓	Natl Std. ⁴⁷	4.4	INTERFACE MANAGEMENT	
20				✓	Natl Std ⁴⁸	4.7	PART NUMBER CONTROLS	
21				✓	Natl Std ⁴⁹	4.8	CONFIGURATION BASELINE/MANAGEMENT	
22		✓	✓	✓	Q9001-1 Par. 4.5.3 Natl Std. ⁵⁰	4.9	CONFIGURATION CHANGE MANAGEMENT	
23		✓	✓	✓	Q9001-1 Par. 4.5.3 Natl Std ⁵¹	4.9.1	MAJOR ENGINEERING CHANGES	
24		✓	✓		Natl Std ⁵²	4.10	REQUEST FOR VARIANCE	
25			✓	✓	Natl Std ⁵³	4.11	CONFIGURATION STATUS ACCOUNTING	
26			✓	✓	Natl Std ⁵⁴	4.12	DISASTER RECOVERY PLAN	
27			✓		Q9001-1 Par. 4.8	4.13	PRODUCT SERIALIZATION	
28			✓		Natl Std ⁵⁵	4.14	AS BUILT CONFIGURATION REPORT	
29				✓	Q9004-1 Par. 8.5.3 Natl Std ⁵⁶	4.15.1	FUNCTIONAL CONFIGURATION AUDIT	

⁴⁵ EIA STANDARD IS649-95 par. 5.1.6 National Consensus Standard for Configuration Management
“... when there is a rational need ...as appropriate to the product being acquired.”

⁴⁶ ISO 10007:1995-04-15 par. 3.4, 7.3 Configuration Board

⁴⁷ ISO 10007:1995-04-15 par. 7.2.1, 7.4.2 “... evaluation of changes ...”

⁴⁸ ISO 10007:1995-04-15 par. 5.2.3 & 7.2.3

EIA STANDARD IS-649-95 par. 5.2.3.d Product Identification

⁴⁹ ISO 10007:1995-04-15 par. 3.3, 5.2.4 & 7.2.4

⁵⁰ ISO 10007:1995-04-15 par. 7.4

⁵¹ EIA STANDARD IS-649-95 par. 5.3(b) Change Management; par. 5.3.1.2(a) Major

ISO 10007:1995-04-15 par. 7.4

⁵² ISO 10007:1995-04-15 par. 7.3, 7.5.2

EIA STANDARD IS-649-95 par. 5.3.4

⁵³ ISO 10007:1995-04-15 par. 7.5.3 CSA Reporting

EIA STANDARD IS-649-95, par. 5.4

⁵⁴ ISO 10007:1995-04-15 par. 5.3 Configuration Control - disaster recovery

⁵⁵ ISO 10007:1995-04-15 par. 7.6 Configuration audit procedure as-built/produced

EIA STANDARD IS-649-95, par. 5.5 Figure 12

MIL-STD-973 (4/17/92) Configuration Management (Military Standard) App. H Task 501

⁵⁶ ISO 10007:1995-04-15 par. 7.6 Configuration Audit Procedures

	A	B	C	D	Source or ISO Par.	BPM Par. No	REQUIREMENTS Supplier shall document, maintain, describe, provide or demonstrate:	Supplier Procedure & Paragraph
30		√	√		Natl Std ⁵⁷	4.15.2	PHYSICAL CONFIGURATION AUDIT	
31	√	√	√	√	Q9001-1 Par. 4.2	5.0	QUALITY SYSTEM	
32	√	√	√	√	Q9001-1 Par. 4.17	5.4	QUALITY SYSTEM DOCUMENTATION	
33			√		Mil	5.5.2	INITIAL LOT VALIDATION	
34			√		Q9001-1 Par. 4.10.3	5.5.3	IN-PROCESS INSPECTION	
35		√			Q9001-1 Par. 4.10.4	5.5.4	FINAL INSPECTION	
36			√		Q9001-1 Par. 4.10.4	5.5.5	CUSTOMER WITNESS OF FINAL INSPECTIONS	
37	√	√	√		Q9001-1 Par. 4.12	5.6.3	INSPECTION & TEST STATUS	
38	√	√	√		Q9001-1 Par. 4.13 Par. 4.13.2	5.6	NONCONFORMING PRODUCT DETERMINATION AUTHORITY	
39	√	√	√	√	Q9001-1 Par. 4.16	5.7.1	RECORD RETENTION	
40		√	√	√	Q9004-1 Par. 5.6	5.8	CONTINUOUS IMPROVEMENT PROGRAM	
41		√	√	√	Q9004-1 Par. 6.2.2 a)	5.9	COST-OF-QUALITY	
42	√	√	√	√	Q9001-1	6.0	SUPPLIER SELECTION	
43	√	√	√	√	Par. 4.6.2 Best Pract. ⁵⁸	6.1	POLICIES, PROCEDURES AND PLANNING	
44	√	√	√	√	Q9001-1 Par. 4.6.2c	6.4	SUPPLIER PERFORMANCE RATING SYSTEM	
45	√	√	√		Q9001-1	7.0	PROCUREMENT CONTROLS .	
46	√	√	√	√	Par. 4.6 Par. 4.6.3	7.1	PROCUREMENT PROCEDURES	
47	√	√	√	√	Q9001-1 Par. 4.1.3 Par. 4.17	7.4	PROCUREMENT SYSTEM EVALUATIONS	

⁵⁷ ISO 10007:1995-04-15 par. 7.6 New Part Launch par. 5 pg. III-22
⁵⁸ TRW AEN Automotive Supplier Development Manual, 9/96 pg. III-2

	A	B	C	D	Source or ISO Par.	BPM Par. No	REQUIREMENTS Supplier shall document, maintain, describe, provide or demonstrate:	Supplier Procedure & Paragraph
48	✓	✓	✓		Q9001-1 Par. 4.7	8.0	CUSTOMER PROPERTY CONTROLS	
49	✓	✓	✓	✓	MIL ⁵⁹	8.1	CUSTOMER PROPERTY POLICIES, PROCEDURES AND CONTROL PLAN	
50		✓	✓	✓	Q9001-1 Par. 4.7 Par. 4.15.5	8.3	CUSTOMER PROPERTY IDENTIFICATION, CARE AND REPORTING	
51		✓	✓	✓	MIL ⁶⁰	8.4	DISPOSAL OF CUSTOMER PROPERTY	
52	✓	✓	✓	✓	Q9001-1 Par. 4.15 Par. 4.15.1 Par. 4.15.4	9.0	HANDLING, STORAGE, PACKAGING & DELIVERY	
53						9.1	HANDLING AND PACKAGING POLICIES, PROCEDURES	
54	✓	✓	✓	✓		9.2	PACKAGING	
55	✓	✓	✓	✓	Q9001-1 Par. 4.15.4 MIL ⁶¹	9.3	BAR CODING	
56	✓	✓	✓	✓	Q9001-1 Par. 4.15.5	9.4	HANDLING, PRESENTATION AND PROTECTION	
57	✓	✓	✓		Q9001-1 Par. 4.9	10.0	PRODUCTION PROCESS CONTROLS	
58	✓	✓	✓	✓		10.1.1	MANUFACTURING PLANNING	
59		✓	✓	✓	Q9001-1 Par. 4.9e Par. 4.11	10.1.2	APPROVAL OF MANUFACTURING OR ASSEMBLY PROCESS	
60		✓	✓		Q9001-1 Par. 4.9d Par. 4.10	10.1.5	PROCESS CAPABILITY STUDY	
61			✓		MIL	10.2.1	REPORTING PROCESS CONTROLS AND IMPROVEMENTS	
62			✓		Best Pract.	10.3	DEMONSTRATION OF OPERATIONAL CONTROLS	

⁵⁹ FAR 52.245 Government Property (Fixed-Price Contracts)

⁶⁰ FAR 52.245-2 (i) Final Accounting and disposition...

FAR 45.6 Reporting, Redistribution, and Disposal of Contractor Inventory

⁶¹ MIL-STD-2073 (10/96) DoD Standard Practice for Military Packaging Par. 4.1.1;
MIL-STD-130 (6/1/97) Identification Marking of US Military Property (Standard Practice)

	A	B	C	D	Source or ISO Par.	BPM Par. No	REQUIREMENTS Supplier shall document, maintain, describe, provide or demonstrate:	Supplier Procedure & Paragraph
63		√	√		Best Pract.	10.4.1	VARIABILITY REDUCTION INSTRUCTIONS	
64	√	√	√	√	Q9004-1	11.0	PRODUCT SUPPORT AND LOGISTICS	
65	√	√	√	√	Par. 16.4.3 Par. 16.4.4 Best Pract. ⁶²	11.2	PRODUCT SUPPORT PLAN	
66				√	MIL ⁶³	11.3	TRANSFERRABLE TECHNICAL DATA PACKAGE	
67				√	Best Pract.	12.0	Reliability	
68				√	Best Pract.	12.8	RELIABILITY PROGRAM	
69				√	Q9004-1 Par. 16.5 Par. 16.6	12.9	FAILURE REPORTING	

⁶² Ref. MIL-HDBK-502, 5/30/97

⁶³ MIL-DTL-31000 Technical Data Package, 6/9/97

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

PROGRAM CONTROL PLAN

IBP/MPCL PROGRAM (Example)

Using Business Practices Manual
and Operational Requirements Matrix

Date: 21 April 1998

Rev: Original

Prepared By: _____
J. Ronald McDonald

Certification that all customer requirements are complied with as described in our internal procedures and this document:

_____ **Date** _____
TRW AEN Program Manager, Len Groth

_____ **Date** _____
TRW AEN Quality Assurance, Fran Pepper

Customer Acceptance:

_____ **Date** _____
TRW ASD IBP Program Manager, Chuck Ebeling

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

CHANGE CONTROL

REVISION	DATE	AUTHORIZATION	REVISION/CHANGE DESCRIPTION	PAGES AFFECTED
Original	4/21/98	J. R. McDonald	Incorporate input from AEN	ALL

REFERENCE DOCUMENTS

IBP Military Products from Commercial Lines, Business Practices Manual
ISO Q9002-1994; Quality Program Requirements

INTRODUCTION

This Program Control Plan is designed to comply with the intent of customer requirements as stated in the contract, in the Business Practices Manual Par. 1.4, and in ISO Q9001-1994 Par. 4.2.3.

TRW AEN has received (1/5/97) the 3rd party QS-9000 certification.
QS-9000 is the Automotive Industry Association's adaptation of ISO-9000 Quality System requirements. TRW AEN systems are compliant with QS-9000 and are therefore compliant with ISO Q9001-1994.

NOTE: TRW ASD actions and responsibilities are shown in BLUE ITALIC format for clarification of program continuity only.

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

1. ORGANIZATIONAL & TECHNICAL INTERFACES

Ref. Business Practices Manual Par. 1.2

Ref. ISO Q9001-1994 Par. 4.1.2

1.1 IBP Program Management Organization

IBP has established a multi-functional Integrated Product Team including:

- Wright Laboratory/Manufacturing Technology (WL/MT)
- TRW Avionics Systems Division (ASD)
- TRW Automotive Electronics North America (AEN).

Ref. AEN SPI 160 CDP Pg. I-9-12

1.2 IBP IPT Organization

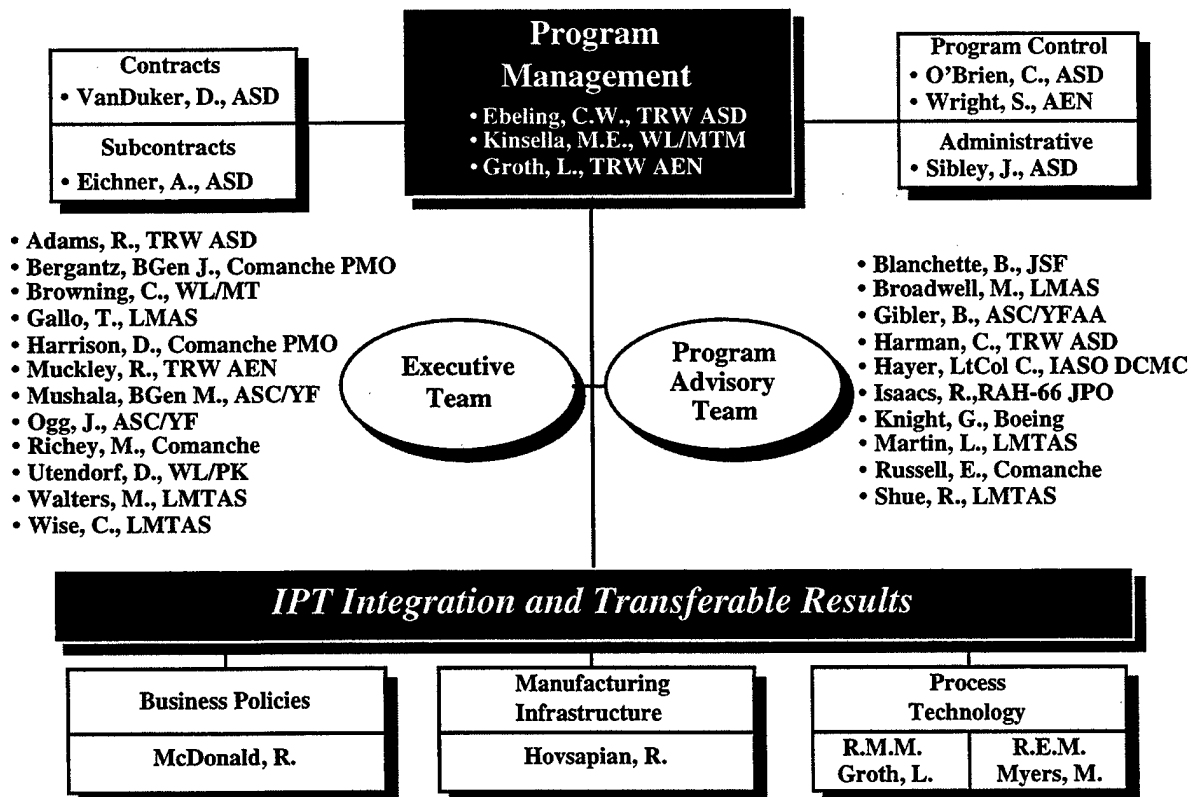


Figure 3. IBP Program Organization

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

1.3 Program Contacts at TRW AEN

Name	Program Function	Telephone/FAX
Len Groth	IBP AEN Manager	217-826-3011 ext. 2455
Fran Pepper	Quality Manager	ext. 2341
Judy Stone	Engineering Services Mgr.	ext. 2324
John Van Sandt	Quality Engineer	ext. 2345
Ron Hill	Product Engineer	ext. 2250
Allen Kerr	Process Engineer	ext. 2426

Table 3. TRW AEN Contacts

1.3.1 Program Manager

TRW AEN has appointed Len Groth as program manager for day-to-day decisions and interface with TRW AEN at Marshall, IL and Farmington Hills, MI and for interface with the IBP/MPCL Integrated Support Teams. This manager reports Rusty Burrell, Manager Manufacturing Engineering, Marshall IL. Operations.

1.3.2 Quality Engineer

A Quality Engineer, John Van Sandt has be assigned to the program to assure that quality tasks are adequately defined and implemented. He will control the quality assurance program without regard for organization's boundary by monitoring the overall quality effort and by making periodic reports to Program Management.

2. PROGRAM CONTROL PLAN

Ref. Business Practices Manual Par. 1.4

Ref. ISO Q9001-1994 Par. 4.2.3 Quality Planning

TRW ASD actions and responsibilities are notes shown in BLUE ITALIC format for clarification of program continuity only.

A review of contract (AEN OP 4.3.1) and Quality Function Deployment (QFD) was completed in October 1994. The Operational Requirements Matrix was subsequently completed in November 1996 by a cross-functional team, to identify requirements regarding all contract phases i.e., design, manufacture, inspection, test, delivery.

This Program Control Plan (AEN OP 4.2.3) describes the processes that will be used to satisfy the customer requirements that are currently outside of the QS9000-certified TRW AEN internal

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

policies, procedures and processes.

3. SCHEDULE OF KEY PROGRAM EVENTS

Ref. Business Practices Manual Par. 1.4.1

Instructions: Key program events are maintained and provided to the customer.

Ref. SPI 160 CDP par. 1.2.7

ACTIVITY	SCHEDULE DATE
<i>Design Reviews</i> ASD	<i>On-going to 3/97</i> Completed
<i>Design Verifications</i> ASD	<i>FCA = 2/3/98 @ ASD</i>
Configuration Audits	<i>FCA = 2/3/98 @ ASD</i> <i>PCA = 4/98 @ AEN-Marshall, IL.</i>
Trial Run or Proto-type	<i>1/97 thru 3/98 (DV)</i> Completed
Program Control Plan	<i>3/11/98</i> Completed
Production Validation	<i>PCA = 4/98 @ AEN, Marshall (PV)</i>
Product Delivery	<i>75 ea. PNP 8/98; 41 ea. FEC 8/98</i>
<i>Qualification Testing</i> ASD	<i>6/98 (F22 SoF) After IBP</i> POST-IBP
<i>Acceptance testing</i> ASD	<i>6/98</i> POST-IBP

Customer and members of the IPTs will be advised of significant changes in the schedules during the Quarterly Self-assessment meetings.

4. CUSTOMER PARTICIPATION PLAN

Ref. Business Practices Manual Par. 1.4.2

TRW AEN uses the concurrent development process (CDP, SPI 160) to measure progress and make adjustments to product introduction schedules. We will use this system for IBP as it relates to manufacturing, customer involvement and recommend the customer participation would take place at the End-of-phase Exit Reviews .

Phase Exit Review (PCA) Attendee:

1. Customer (Air Force Rep) TBD
2. IBP Program Mgr. (ManTech).....M. Kinsella
* Contractually required for IBP customer to witness 15 minute change-over.
3. IBP Program Mgr. (TRW ASD) C. Ebeling
4. IBP Program Mgr. (TRW AEN).....L. Groth
5. PT Team Leader.....M. Myers
6. PT RMM.....M. Myers
(includes Lockheed & Boeing PT representatives)
7. MI Team Leader.....R. Hovsopian
8. BP Team Leader.....R. McDonald

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

Due to the nature of IBP program, several demonstrations may be required that are not normally done in commercial industry. Additional participants beyond the normal customer/supplier relationship (ASD/AEN) may be invited for reviews. The customer representatives may include:

- *IBP Program Manager for TRW ASD*
- *IBP Program Manager for WL/MT*
- *IBP Process Technology Team Manager*
- *IBP Program Manager for TRW AEN*
- *TRW ASD Configuration Management Manager*
- *USAF F22 System Program Office*
- *Lockheed Martin Aerospace System*
- *Lockheed Martin Tactical Aircraft System*
- *Boeing/Sikorsky RAH-66 JPO*

Customer may conduct, witness, or monitor inspections or tests required to substantiate product conformance to Engineering drawings, specifications, and contract requirements at TRW AEN facilities when such activity does not disrupt the manufacturing process flows.

5. DESIGN REVIEWS

Ref. Business Practices Manual Par. 2.0

IBP designs are being created at TRW ASD, with the manufacturing support of TRW AEN. Design reviews are the responsibility of TRW ASD and will be supported as necessary (DV, MRR, PV) by TRW AEN. These Design Reviews are conducted by the Integrated Product Development Team (IPDT) on a 4-6 week basis with the Design Verification scheduled for February 3, 1998 in San Diego.

5.1 Customer Verification (CDR)

Ref. Business Practices Manual Par. 2.9.4

CDR was conducted in Marshall, IL. in March 1996 and included several Technical Interchange Meetings during the evolution of the design.

5.2 Customer Verification (PV)

Ref. Business Practices Manual Par. 4.16.3, 5.6.1.2

Manufacturing Readiness Review including Physical Configuration Audit will be conducted by AEN and ASD PT members in Marshall, IL in March 1998. Tasks to be completed:

- Review of first lot of production validation hardware (5.6.1.2)
- Hardware is produced in accordance with released design documentation (Physical Configuration Audit) (4.16.3)
- Customer requirements are satisfied
 - 15 minute production line change over to be demonstrated

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

- 75 ea. PNP Modules
- 41 ea. FEC Modules

6. REVIEW AND AUTHORIZATION OF CHANGES

Ref. Business Practices Manual Par. 4.4, 4.10, 4.10.1

The change control system (AEN SPI 160, CM 4.5.2-1 and CM 4.5.3) provides for documentation, approval, implementation, and verification of changes on technical and hardware documents, and changes which require established points of effectivity.

Configuration Management procedures assure that current drawings, specifications, and changes are forwarded to operating personnel as they are released.

AEN Operating Procedures Manual Section II OP 1.01 Par. 6.4 - Engineering support notifies the customer when part number, engineering change level, manufacturing location, material subcontractor and production process environment are changed. A determination is made with the customer as to whether the item needs to be re-qualified. Engineering drawings and documents and changes thereto are prepared and controlled in accordance with Configuration Management Procedures.

Ref. Business Practices Manual Par. 4.4 Change Control Board (CCB)

TRW AEN uses a cross-functional team according to CM 4.5.3-2 configuration changes. This team consists, as required, of Quality Engineering, Manufacturing Engineering, and Design Engineering who are responsible for reviewing technical documents; i.e., Specification or Source Control Drawings, test procedures, drawings, fabrication, and planning documents for compliance to design and quality requirements. AEN DCN form FO102 has customer interface requirement and authorization. Customer approval is the responsibility of the Marshall P.E.M or FHMI. P.D.M.

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

Document Approval	COMPONENTS		ASSEMBLIES & DETAILS	
TRW:	ASD	AEN	ASD	AEN
P.N.		X	X all others	Module P.N. (Highest Level)
CM Control		X		X
Drawn By	X		X	
Quality	X			X
Engineering	X		X	
Check		X		X
Manufacturing		X		X
IPT Lead			X	

Note: Review and authorization of Variances is addressed below in #0 11. Control of Nonconforming Products.

7. MATERIAL ACQUISITION AND INSPECTION

Ref. Business Practices Manual Par. 8.3

Material purchased by TRW AEN (per OP 4.6.1, SPI 450) shall be shipped to Marshall, IL and received and inspected per AEN's established procedures (per OP 4.10.1).

TRW ASD material shall be purchased on a purchase order with a Q-1 Quality clause (count and damage at receiving) and shall be received against the appropriate purchase order line item. These parts shall be processed through receiving inspection and stored in the contract stores area. Material shall be issued to IBP manufacturing representatives using a Contract Material Requisition (CMR). TRW AEN may request that, for tracking purposes, such material transfer to us by means of a no value Purchase Order issued by TRW AEN to TRW ASD.

Material may be drop-shipped to TRW AEN and received per TRW AEN's procedures with notice of receipt sent to TRW ASD's IBP Material Planner.

8. MODULE HANDLING & MARKING

Ref. Business Practices Manual Par. 4.14, 5.8, 9.3

Modules received from TRW AEN will be bar code marked per the assembly drawing including, part number, revision letter and serial number.

These modules will be processed at TRW ASD under a note receiver, will not require receiving inspection, and will be issued to the manufacturing representative. The ASD manufacturing

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

representative will document all operations, including rework and testing performed on the module. This documentation will be primarily performed using the local extension (in San Diego) of the TRW AEN Computer Integrated Manufacturing (CIM) System.

PV module Acceptance Test Procedure (ATP) and Environmental Stress Screening (ESS) will be documented with the appropriate F-22 test data sheet. In the event that the CIM system is unavailable, events logs shall be used and the data from them transferred into the AEN CIM prior to module delivery to the IBP customer.

In the event of the module rework, repair, or retest at TRW ASD, such operations will be authorized by the manufacturing representative and documented in one of the methods noted. Inspection of rework/repair performed on the modules at TRW ASD will be the responsibility of the TRW AEN representative or their delegate. TRW ASD inspection will not be required on IBP hardware. However, adequate quality and manufacturing records will be maintained (per BPM 5.8).

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

9. AS BUILT CONFIGURATION REPORT

Ref. Business Practices Manual Par. 4.15

Product structure and parts traceability data is available in the manufacturing CIM system.

Product is built to the latest released BOM at all times. This report will be provided in a format determined by the AEN information systems department.

The As Built report format will be established during Production Validation. All information for a product part number e.g. bill-of-material, current revision, bar code serial number and material sequence numbers is available in the CIM system. Component suppliers and material date codes can be traced through the sequence numbers.

As-built reports will be available after first pre-PV runs. PNP target date is after 3/20/98. FEC is early April, '98.

10. Physical Configuration Audit

Ref. Business Practices Manual Par. 4.16.3

Will be conducted as a part of the PV (# 0 above).

Physical Configuration Audit will be conducted in accordance with the PCA LEVEL 3 requirements (BPM 4.16.3).

11. Control of Nonconforming Products

Ref. Business Practices Manual Par. 5.7

Requirement: Final determination by the customer for "use as is" or "repair" dispositions and for any major nonconformances is applicable to a cost-type contract.

Ref. AEN OP 4.13.1 Par. 5.5; OP 4.13.1-1 Par. 3.1

TRW AEN does not ship any nonconforming product to a customer. There is no need for approval to ship product with "variances". The product is either reworked to meet requirements or is replaced. "Use as is" and "repair" are not permitted dispositions for customer product in the TRW AEN procedures.

11.1 Nonconforming Materials/Component Identification & Segregation

Nonconforming material or components are segregated from acceptable materials or production flow by placing them in designated areas that are controlled and dispositioned by an authorized Material Review Board (MRB). MRB dispositions for material or components will include rework, return to vendor, or scrap.

- "rework" - vendor product is reworked to meet the requirements of the specification
- "return to vendor" - product is returned from receiving inspection to the supplier for rework to requirements or replacement.
- "scrap" - vendor product is permanently and positively identified to preclude unauthorized use

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 11:59 AM

12. MANAGEMENT OF CUSTOMER-OWNED PROPERTY

Ref. Business Practices Manual Par. 8.3, 8.4, 8.5

Ref. TRW AEN OP 4.7.1 Control of Customer Supplied Product.

When Customer furnished property is found to be damaged, malfunctioning, or otherwise unsuitable for use, such conditions will be reported promptly to the appropriate Customer Representative.

- • Examination upon receipt, to detect damage in transit (OP 4.7.1 Par. 5.2)
- • Ensure articles received are as specified in shipping documentation
- • Protection, maintenance, calibration, periodic inspection, and controls necessary to preclude damage or deterioration during handling and storage (OP 4.7.1 Par. 5.3)
- • Protection from improper use
- • Disposal of Customer-furnished property. (See 0 below)

12.1 Disposal of Customer Property

Ref. Business Practices Manual Par. 8.5

Disposal is outlined in AEN document MAM 1.1 Par. 3.4

Persons initiating equipment dispositions (scrap, sell, storage, transfer, customer returned equipment) must complete an Equipment Disposition form (F0256) and route for proper signature approval. Customer approval is required prior to the disposition of customer-owned equipment or tooling. (Underlined sentence is stated in F0256 document.)

13. CONTRACT COMPLETION BY TRW ASD

Ref. Business Practices Manual Par. 8.3, 8.4, 8.5, 9.0, 9.4

NOTE: Upon receipt of modules from TRW AEN for further processing and testing at ASD, the TRW ASD property administrator shall:

- a) verify condition and identify customer property upon receipt;
- b) provide care and maintenance and storage
- c) ensure customer product is not physically commingled "segregation of product"

When these modules have completed assembly and testing, a "DD250" shall be prepared at TRW ASD and used to deliver the modules "in place" to the IBP customer. The IBP modules will be tagged as Government Property by the TRW ASD property administrator and shall be tracked and logged per TRW ASD procedures.

Finished modules that are not required by F-22 or RAH-66 shall be stored in the controlled IBP Finished Goods area. The finished IBP modules will be delivered to the F-22 / RAH-66 integration lab at TRW ASD for system integration upon completion of a DD 1149 transfer

TRW Automotive Electronics	
Program: Industrial Base Pilot PROGRAM CONTROL PLAN	DATE 5/26/99 12:11 PM

document as agreed in the TRW-WL/MT Transfer Agreement.

Disposal or return of any IBP-owned modules will be in accordance with properly authorized, written direction of the WL/MT customer.

3. Parts Control

Objective: To reduce product cost by selection of a component's performance, quality, durability, maintainability and reliability.

A Parts Control Program⁶⁴ is an industry "Best Practice" for the selection of parts or materials during the product life cycle. A Parts Control Program is obviously more applicable during the design phase, but is also applicable when obsolescence, modifications, or reliability become an issue after product development. A Parts Control Program is established to:

- achieve life cycle cost savings or cost avoidance,
- reduce parts proliferation in a product or system (reduce the number of part types, grades or values),
- minimize the affect of parts obsolescence , and
- improve interchangeability, reliability and maintainability.

A world-class parts or material selection process includes such activities as Integrated Product Teams (IPT) with customer involvement and sub-tier supplier alliances and shared databases to evaluate various technologies and performance characteristics of candidate parts as compared to the design requirements.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix.⁶⁵ The supplier's own processes or systems must meet the intent of ISO 9001 and these requirements. The following requirements for policies and/or procedures are established:

Requirement Title	Par.
1. 3.1 Parts Control Program and Planning.....	3.1
2. 3.4 Customer Notification of Product Changes.....	3.4

The Automotive Industry Association and commercial companies such as Boeing Commercial Avionics Systems have developed parts control program requirements. Many of these programs evolved from, and make reference to, the MIL-STD-965A specification which was replaced by MIL-HDBK-965 in September 1996.

3.1 Parts Control Program and Planning

The supplier should have a facility-wide documented Parts, Material, and Process Control Program for the selection and use of parts, materials, and processes in the design and

⁶⁴ Boeing Defense and Space Group, Commercial Avionics Systems - (BD&SG-CAS) D900-10193-1 Parts Control Program

⁶⁵ Organizational and Technical Interfaces BP Requirements Section 1

manufacturing of the product. It is a best practice found in commercial and defense industries that the supplier adopt a cross-functional team⁶⁶ culture for parts selection. The typical Parts Control Program includes the following formalized processes.

- Internal approval process including: organizational and technical interfaces for design activities,⁶⁷ and identification of Parts Control Board members, if applicable.
- Order of part preference or level of authorized use (i.e., disapproved for use, limited use, conditional use, or preferred use) including applicability definitions as determined by supplier's process.
- New parts selection or substitution procedures considering cost, availability, quality of parts or material while minimizing the need for customer oversight, ability for future upgrades, emphasis on process controls in manufacturing, and management of new suppliers who will support the design and production objectives.
- Part standardization for compatibility with manufacturing processes, and reduction of parts types and values within the product or system. Preferred parts should be identified for use by the designers.
- Parts obsolescence - with the lengthy design and development cycles, it is critical for "out-of-production parts" to be addressed as early as possible.
- On-going product supportability (reliability, maintainability, logistics) efforts
- Qualification to customer requirements for reliability and performance of parts or material
- Formal customer approval for a specified part number, manufacturer, production process and location, engineering change (revision) level to be authorized for use in the specific product⁶⁸ including an order of preference or level of authorized use. Those parts that are selected for use in a product design may require parts approval or product qualification prior to beginning production by either the commercial or DoD customer.
- Notification to customer of potential product performance issues or delivery schedules.
- Component database or library for collection of all parts and material information including reliability reports and part qualification data, specifications, data sheets, test results, trade studies, and analysis and exchange of this information with the customers and preferred suppliers.

Supplier shall describe its internal parts control⁶⁹ procedures and processes for selection, qualification, standardization, approval and data collection for parts to be used in the product design and manufacture.

66 See Section 1.0 Organizational and Technical Interfaces
Parts Acquisition Reform Team BEST PRACTICE 4/30/96, pg. 6 Design Process

67 ISO Q9001-1994 par. 4.4.2 Design and Development Planning
ISO Q9001-1994 par. 4.4.3 Organizational and Technical Interfaces

68 QS-9000 Quality System Requirements, Section II pg. 52
Automotive Industry AIAG Production Part Approval Process (PPAP)

69 ISO Q9001-1994 par. 4.4.2 Design & Development planning

When the supplier's existing parts control procedures and systems do not adequately address customer requirements, a Parts Control Plan is developed in sufficient detail to clearly describe the supplier's parts control organization and intended approach for selection, standardization, qualification, substitution and alternate parts, approval process and data collection for parts to be used in the product design to ensure that stated performance and reliability requirements are satisfied. This Parts Control Plan typically requires customer approval prior to implementation or for any changes affecting the intent of the plan and may be combined with the overall Program Control Plan.

3.2 Supplier Component Library

This process for compiling parts information is determined by the supplier and may take the form of an on-line database (i.e., Parts Data Management or MRPII system) or may be a design-tool component library. The supplier may be required to demonstrate their process for collection and use of parts information during the supplier selection process.

A component database or library is a "best practice" and is essential to accomplish cost savings and schedule improvements mandated by customers. Typical advantages of a component library include the following.

- Accelerates the design cycle time by providing designers with parts to choose from that have been previously approved. Parts reliability and qualification information is available and suppliers are pre-approved.
- Reduces the variety of values within a parts family, thereby increasing the potential quantity to be purchased and reducing the parts costs.
- Provides procurement with the opportunity to forecast parts usage and provide for grouping of acquisitions with sub-tier suppliers and thereby improving the parts availability and costs.

A typical parts information and data collection system includes elements which provide useful information for electrical and mechanical parts or assemblies for use in design, acquisition, inventory and logistics or repair activities.

- Basic Part Information
- Form, Fit, Function, Interface
- Qualification and reliability
- Standardization
- Special Characteristics⁷⁰
- "Where used" (Reverse Bill-of-Material)
- Robust Design models and analysis tools

BOEING CAS: D900-10193-1 Pg. 15 par. 3.1 Parts Control Plan
70 Advanced Product Quality Planning and Control Plan (Automotive Industry AIAG) par. 2.8 pg. 16

3.3 Shared Databases

It is desirable that a component database of relevant information be accessible to industry, customers and suppliers. Use of shared databases⁷¹ will increase the parts knowledge base for all participants. A shared database will reduce the product costs by providing information for increased parts standardization and will reduce the suppliers' costs associated with qualification, redundant testing, re-design activities, and component failures or obsolescence.

3.3.1 Government Industry Data Exchange Program (GIDEP)

An example of a shared database is the Government Industry Data Exchange Program (GIDEP) database which is available free of cost to all suppliers who provide products to the Government. This database only requires participation and submission of parts information including: engineering, failure experience, metrology, reliability and maintainability and other product information.

GIDEP Operations Center
2300 5th Street, Norco, Ca 91760
Mailing address: PO Box 8000, Corona, Ca 91718-8000
Voice: (909) 273-4677 FAX: (909) 273-5200
http://www.gidep.corona.navy.mil/data_inf/faq.htm

3.4 Customer Notification of Product Changes or Phaseout

The supplier shall establish, document and maintain as necessary a process for advanced customer notification⁷² of proprietary product phaseout or of changes to any product that may affect the customer's intended application's form, fit, or function.

As a member of the customer's Integrated Product Team, the sub-tier supplier should willingly provide ample warning of impending changes to critical components used by his customer. The sub-tier supplier should advise the customer of all changes to proprietary products or to any product for which the supplier has design responsibility, which affect the customer's form, fit, function or interface attributes applicable to device family, and allow ample time for the customer to assess changes and potential re-qualification requirements. Failure to provide this notice, may cause the customer to lose market position, thereby losing profits and jeopardizing the sub-tier supplier's relationship. This requirement is closely aligned with design controls and configuration management requirements for customer notification and approval of changes affecting a customer's product design; however, this requirement is aimed toward the continued customer relationship when the supplier has control of the design.

71 Parts Acquisition Reform Team BEST PRACTICE 4/30/96, pg. 16 Shared Database
(Lockheed Martin, McDonnell Douglas, Hughes)

72 QS-9000 Quality System Requirements, Section II pg. 52, Production Part Approval Process

3.5 References

Additional sources of parts control information.

- Parts Control Best Practices, Parts Acquisition Reform Team, Government/Industry Support Team, April 30, 1966: McDonnell Douglas, Hughes, Lockheed Martin
- CAS Electrical/Electronic/Electromechanical Parts Control Operating Plan
Boeing Defense & Space Group, Commercial Avionics Systems 8/10/86
- Product Part Approval Process, Automotive Industry Action Group, 2/1993

Attachment A - Parts Control Program

Note: This attachment is NOT a requirement, but is provided as a "best practice".

3.6 Parts Control Program Guide

This attachment is provided to express the level of detail desired of defense suppliers, to highlight the subjects of interest, and to provide examples of parts selection programs. It is intended that the suppliers can establish, or supplement, their parts & materials management programs to accomplish the specific defense requirements as stated in the Statement of Objectives.

Parts and raw materials are the building blocks of all systems. It is imperative that they be selected and applied in a manner that ensures their "robust" use for the particular conditions under which they must operate⁷³. A "robust" product/process design will function with limited variability in spite of diverse and changing conditions of the military environment or component-to-component variations.

Any parts control system should focus on two primary goals:

- The selection of parts and materials which reliably perform the needed function for the design life of the equipment, in the environment in which they are intended to operate.
- To provide cost effective parts and materials throughout the equipment life cycle.

Although raw materials are not discussed separately, most of the concepts and methodologies discussed for parts are also applicable to materials.

Figure 1. Typical IPT Design/Parts Selection Flow provides an example flow chart for the selection of microcircuits, (see Figure 4. Microcircuit Parts Selection Flow on page 66) using the principles discussed in this section.

3.6.1 Integrated Product Team (IPT)

In order to establish a design process which includes the selection of appropriate components, and that responds on a real time basis to rapid changes in design tools and component technology, it is essential for the supplier to adopt an cross-functional team or concurrent engineering culture such as an Integrated Product Team.

Open and frequent communication within this group must exist in order to ensure the successful design and manufacture of a product. It is not, however, necessary to have a separate functional person or group for each of the above disciplines, as long as issues related to each are addressed in the design, parts selection and sub-tier supplier selection processes.

⁷³ Commercial Parts and Practices for Military Applications, Fayette D., MacDiarmid P., et. al., Rome Laboratory, Reliability Analysis Center, June 2, 1995.

3.6.2 Parts Control Plan

The top portion of Figure 1. Typical IPT Design/Parts Selection Flow indicates the elements necessary in the selection of parts and sub-tier suppliers. The center shows the implementation of approved parts as an element of the design/manufacturing process and the bottom shows the key elements of an ongoing product support program.

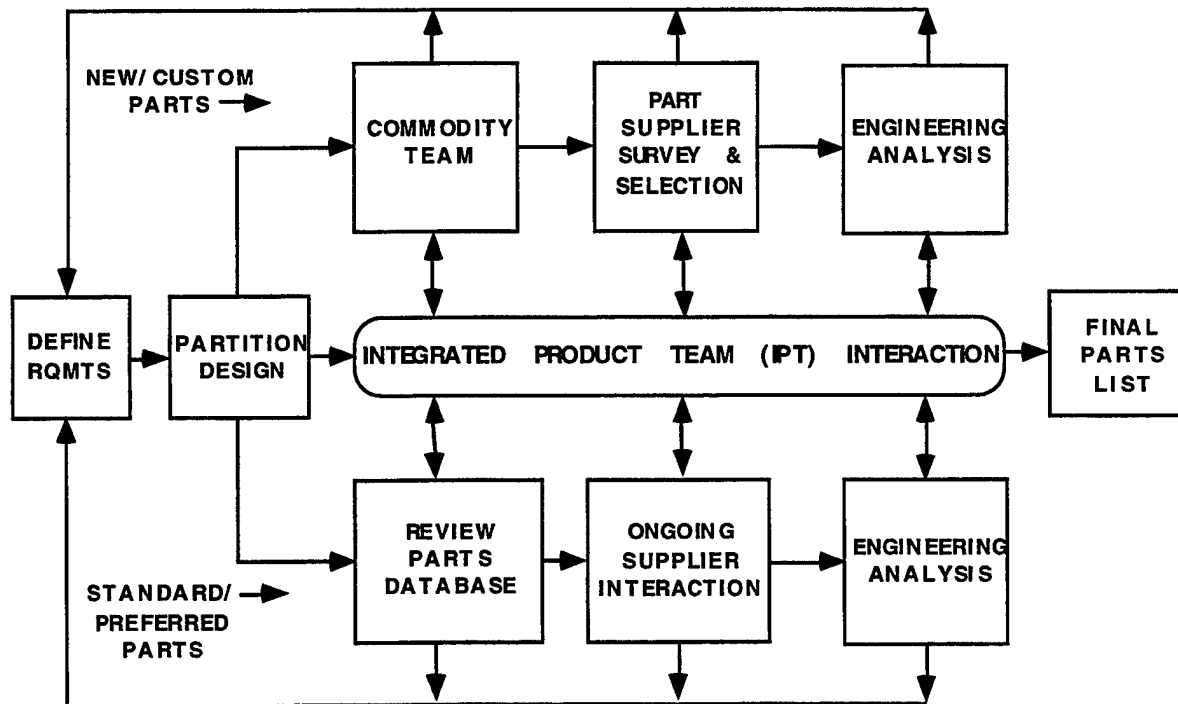


Figure 1. Typical IPT Design/Parts Selection Flow

A parts control plan should ensure that parts and materials will effectively meet the specific application requirements. In general, each supplier should have a comprehensive parts control system that addresses the manner in which the following elements are handled:

- Evaluation and selection of parts and sub-tier suppliers
- Identification of preferred parts and critical parts/technologies/ sub-tier suppliers
- Supportability (standardization, obsolescence, failure analysis, action requests, etc.)
- Data management (data sheets, specifications, sub-tier supplier data)

3.6.3 Parts Selection as an Element of Design

This section of the Business Practice Requirements provides a suggested process for the selection of parts with appropriate and adequate function, performance, reliability, and durability characteristics.⁷⁴

Initially in the design process, there must be a clear understanding of the desired function and performance required, as well as the intended usage of the product including an evaluation of the environment in which the product will perform.

When considering the use of commercial or industrial parts for a military application, parts selection, design, and manufacturing are inseparable processes and require more evaluation than might otherwise be necessary. This is primarily due to a lack of substantial field history of these parts in military environments. Parts selection for military applications needs to move beyond questions of compliance to benchmark standards into questions about reliability and performance in specific applications. The selection process requires the application of rigorous engineering methods, disciplined procurement practices, and the use of reliability, physics-based analytical tools and methods.

Figure 2. Parts Control Process below depicts a parts control model that is typical for defense applications. The Military Parts Control Advisory Group (MPCAG) and Defense Supply Center Columbus (DSCC) Procurement/Supply activity for the Federal Government..

Design guidelines for manufacturing producibility must exist at each supplier. These guidelines establish the limiting constraints imposed on parts selection in terms of package type (size, lead pitch, etc.) and printed wiring board capability (surface mount vs. through hole).

Parts cost and availability are obviously considerations in parts selection. Parts should be selected which are cost effective, yet meet the required performance, reliability, and environmental constraints, and life cycle requirements and should be readily available from more than one source, to meet fabrication schedules, and to ensure their future availability.

Once the supplier has determined that a part is within the company's desired competitive and cost range, the focus turns to specific part application factors. Correct application of parts means "using the best part for the job in an optimum or cost effective manner". The factors to be considered in optimum parts application are both numerous and complex. (see Table 1. Critical Application Factors)

⁷⁴ MIL-HDBK-179A, Military Handbook Microcircuit Application Handbook (7/20/95)

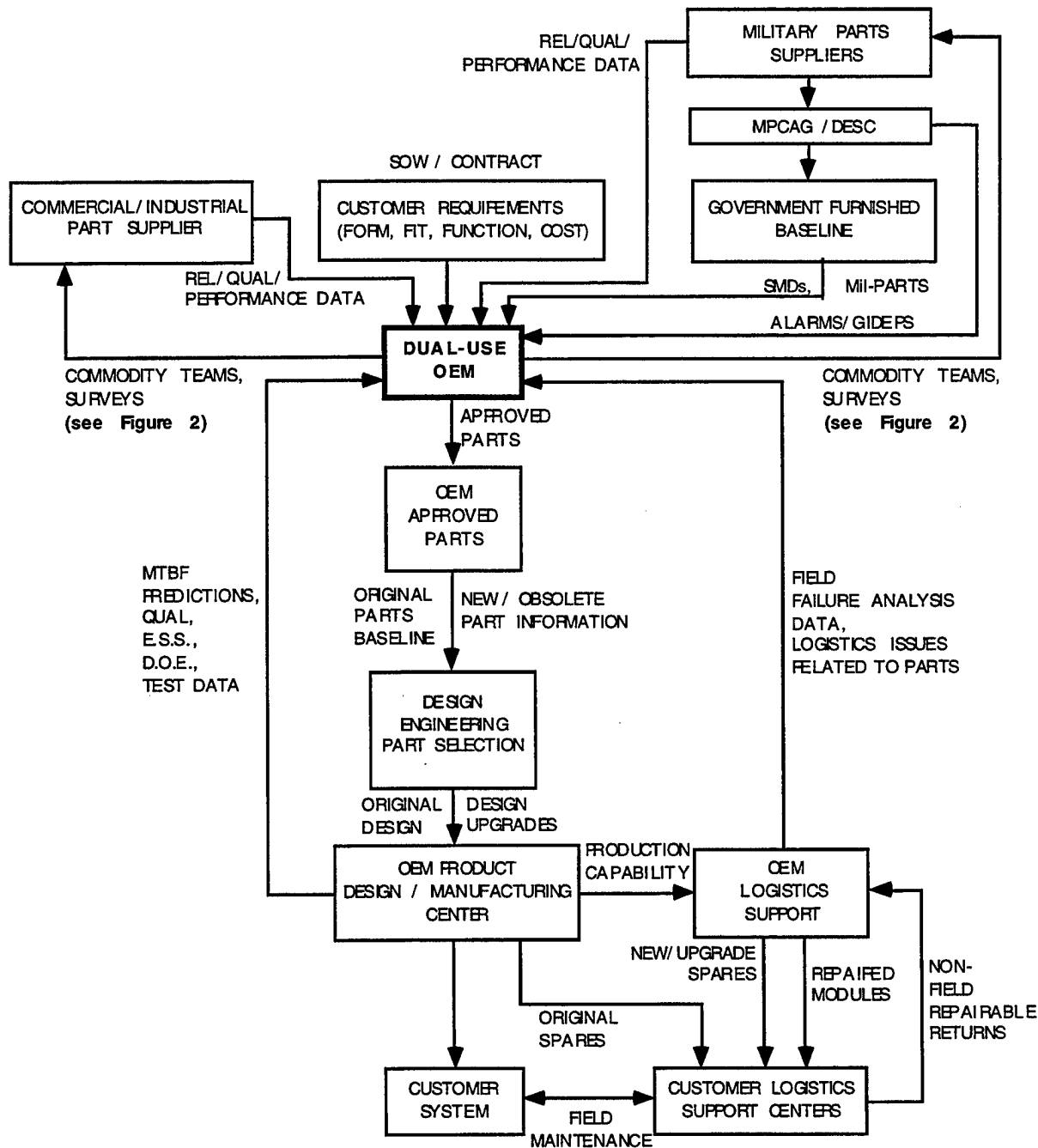


Figure 2. Parts Control Process

Operating Temperature Range- Parts should be selected which are rated for the operating temperature range to which they will be subjected.

Electrical Characteristics- Parts should be selected to meet maximum applied electrical stresses (singularly and in combination), current, voltage, EMI, ESD susceptibility, frequency, waveform and signal requirements.

Stability- Parts should be selected to meet parameter stability requirements based on changes in temperature, humidity, frequency, age, etc.

Tolerances- parts should be selected that will meet tolerance requirements, including tolerance drift over the intended life.

Reliability- Parts should be selected with adequate inherent reliability and properly derated to achieve the required equipment reliability. Dominant failure modes should be considered when a part is used in a specific application.

Life- Parts should be selected that have "useful life" characteristics (both operating and storage) equal to or greater than that intended for the life of the product in which they are used.

Maintainability- Parts should be selected that consider mounting provisions, ease of removal and replacement, and the tools and skill levels required for their troubleshooting / removal/replacement/repair.

Environment- Parts should be selected that can operate successfully in the environment in which they will be used (i.e. temperature, humidity, sand and dust, salt atmosphere, vibration, shock, acceleration, altitude, attitude, fungus, radiation, contamination, corrosive materials, electric and magnetic fields, etc.).

Table 1. Critical Application Factors

In summary, it can be seen that the required information must come from diverse technical disciplines. This reinforces the initial claim that a successful parts selection process requires an Integrated Product Team that works together in real time.

Part Manufacturer Evaluation

As a product's design is developed to meet the system performance requirements, and the need for specific parts is identified, the supplier conducts investigations to evaluate potential part manufacturers and the attributes of the parts to be considered in the design. Two key parts selection issues are:

- Part manufacturers should be chosen which have documented quality and reliability development programs which re-qualify devices when process changes are instituted.

- Part manufacturers should be chosen which have a parts program that requires a continual sampling of their product for qualification testing.

There are many ways in which sub-tier supplier's management and technical capabilities and process controls can be evaluated. See Section 6.0 - Supplier Selection.

3.6.5 Ongoing Supportability Issues

One of the most important aspects of a best practices parts and material management process is the routine performance by the supplier of technology scans to identify emerging trends that could positively or negatively affect product support and field logistics. This practice helps to mitigate the risk of obsolete and out-of-production parts. Technology scans involve the systematic review of emerging technologies in fields that affect a supplier's product.

Government contractors do much of this as part of their Independent Research and Development (IR&D) programs. Attendance at trade shows, subscriptions to newsletters, collaborations with university research programs, and sponsorship of government-industry consortia are other ways of keeping up to date on emerging technologies and the impact on existing and new products. See Section 11.0 - Product Support and Logistics

3.6.5.1 Logistics

Many of the advantages of a preferred part database (par. 3.6.9) are also beneficial to the field Logistics issues related to parts. The overall reduction of parts as a result of implementing a preferred parts database translates to savings to the user in procuring, warehousing, transporting parts and data management, which includes the preparation and maintenance of engineering drawings and other required parts information.

3.6.5.2 Maintainability

The existing concern of losing the initial lower cost advantage of commercial devices through increased life-cycle costs as a result of rework or repair of failed parts, can be alleviated by adopting a parts program that focuses on maintaining a select list of preferred parts that is based on the continuous and concurrent evaluation of current technologies for specific applications.

Suppliers need to be aware of the unique requirements often associated with the defense customer's maintenance of delivered product. Details of field maintenance requirements are usually delineated in the customer's performance specification.

Maintainability issues driven by design parts selection include as an example:

- Removal and replacement of components that have complex package geometry's (fine pitch leads) at minimally equipped or remote repair depots.
- Repair or re-test of designs that use coatings and encapsulants that are difficult or impossible to remove or penetrate.

- Selection of limited-life parts that have diminishing availability and no substitute or alternate replacement part.

3.6.6 Parts Data Management & Utilization

Detailed information regarding parts and materials that suppliers have accumulated over a period of time forms the historical baseline on which future part and sub-tier supplier selections can be based. It is therefore important to establish a working, relational data resource of parts and sub-tier suppliers that the supplier can make use of in a concurrent, real-time fashion. This can be accomplished either through a computer automated system or manually accumulated library. However, as the amount of data increases as well as the need for real-time access by many individuals in the decision process, a computer-based system becomes a more desirable solution.

3.6.7 Parts Database elements

Figure 3. Elements of a Parts Database shows some of the key elements of a relational component database and could be used as a working system for the supplier's design parts and sub-tier supplier selection process. From this system, each of the members of the concurrent team could input or retrieve component and sub-tier supplier-related information.

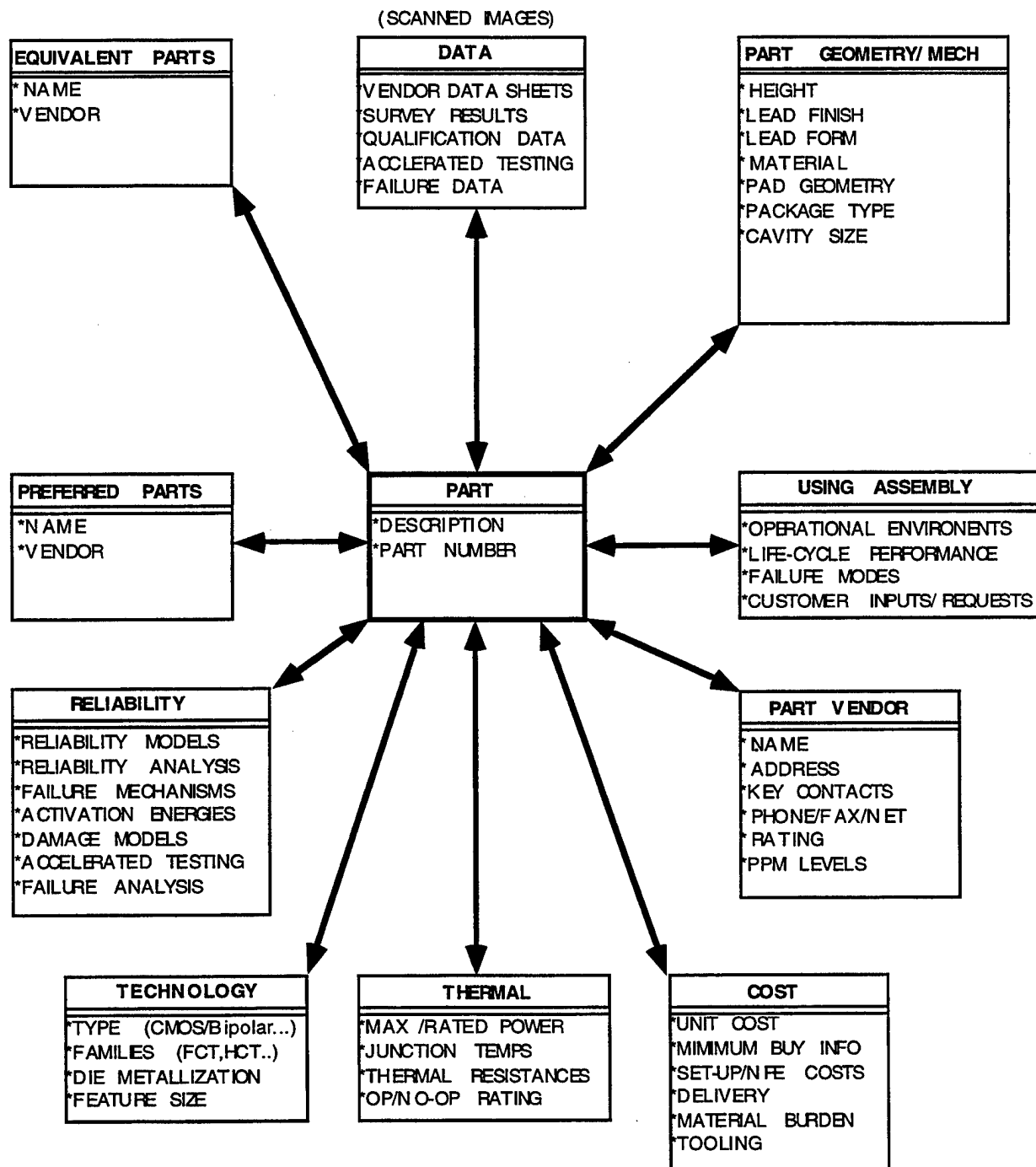


Figure 3. Elements of a Parts Database

A typical database or library may include:

3.6.7.1 Part Basic Information

- 1) Part numbers - generic or sub-tier supplier's, National Stock Number. No substitute available, alternate part available, MIL (military standard)
Military approved components:
JANTX (Joint Army Navy with various levels of product assurance),
MIL-STD (Military Standard),
MIL-PRF (Military Preferred),
QML (Qualified Manufacturing Line)
- 2) Description, nomenclature, brief specification including (a) information source and date, (b) part manufacturers and (c) internal selection or qualification processes.
- 3) Cost Price - ranges and Non-recurring costs offered by various sub-tier suppliers
- 4) Identification of sub-tier suppliers' name, address, phone, identification number, and past performance assessment (quality and on-time delivery). Sub-tier supplier approval should be required prior to parts approval being issued.
- 5) Parts Approval status

3.6.7.2 Form, Fit, Function, Interface (F³I)

- 1) technology (function)
- 2) physical geometry
- 3) package type or interface specifications
- 4) specifications or data sheets
- 5) tolerances
- 6) operating ranges
- 7) thermal characteristics
- 8) special marking requirements
- 9) special packaging for shipment or storage requirements

3.6.7.3 Qualification and reliability

- 1) qualification level: similarity, screening
- 2) source of qualification data: manufacturer, military, internal tests
- 3) reliability data: failure rates, predictions, PPM level, failure analysis data

3.6.7.4 Standardization

- 1) preferred parts - quality and reliability have been established in marketplace or determined by internal qualification and past use.
- 2) commodity code (Federal Supply Code, parts category)
- 3) equivalent part availability
- 4) alternate part identified

3.6.7.5 Special Characteristics⁷⁵

- 1) requiring special attention during design or assembly

3.6.7.6 “Where used” (Reverse Bill-of-Material)

- 1) identify other assemblies using the component

3.6.7.7 Robust Design models and analysis tools:

- 1) Each model is created through a rigorous process which includes extensive checking and validation of the model's correctness.
- 2) schematic symbol models
- 3) functional simulation models
- 4) performance simulation models
- 5) 3D solid models for structural (static and dynamic)
- 6) 2D models for printed circuit board elements.
- 7) thermal analysis

3.6.8 Qualification Data

The parts data management system should provide access to detailed qualification and reliability data supplied by the part manufacturers, together with applicable statistical analyses. It should contain any inspection data (pass/fail criteria, failure resolution or corrective action and re-qualification criteria) obtained from parts suppliers or internal testing and evaluations.

Device qualification data from part manufacturers can be used to verify system environmental qualification requirements provided the data is documented, current, statistically significant, and analyzed to indicate that the parts will function in the environment for the specified life of the product. This data must be continually solicited from the part manufacturers for all the device types utilized and analyzed for the above mentioned attributes. If the device data indicates anomalous conditions, failure analyses conducted, and corrective actions taken by the part manufacturer, then determinations should be made by the supplier for any additional actions that need to be taken regarding this particular device or device type (i.e. date code restrictions, temporary screens, etc.).

The supplier should undertake the following tasks regarding part qualification data prior to utilizing a particular part:

- 1) Part manufacturers shall be contacted to obtain assurances and verification of correct data interpretation.
- 2) Periodic monitoring of data and correlation to in-house and field experience after part is included in the product.
- 3) Review of failure analyses and corrective actions included in the part manufacturer furnished data.

⁷⁵ Advanced Product Quality Planning and Control Plan (Automotive Industry AIAG) par. 2.8 pg. 16

4) The part data should be specifically reviewed for indicators of data integrity (or lack thereof), such as:

- Accuracy of calculations
- Test condition inconsistencies
- Missing samples with no explanation
- Inconclusive failure analyses
- Inconsistent acceleration factors

For cost effectiveness, the utilization of qualification data provided by a part manufacturer for a specific device or device family is the preferred method of qualification. This data should be recorded and retained by the supplier, and should contain the detail part data summary by specific part number. Qualification data should be available at the supplier's facility for internal as well as customer review.

It is important that consideration be given to part-specific configuration issues, particularly that all process change notifications applicable to device families shall be reviewed to assess changes and potential re-qualification requirements.

3.6.9 Preferred Parts

In the course of a design effort, product designers should select parts and materials to meet specified requirements for performance, reliability, quality, producibility and cost. This selection task is greatly benefited if the designer has a list of preferred parts to help in the selection process. Preferred parts are those whose quality and reliability are well-known to the industry, and are, ideally, parts which the supplier has already designed into existing product and has an established success record in the field. Without a preferred parts list, designers will select from the available field of parts with varying degrees of quality and reliability.

Advantages for establishing a supplier preferred parts database are:

- 1) Minimizes the proliferation of parts and materials with identical functions and varying degrees of quality and reliability.
- 2) Minimizes the need for additional engineering justification for new parts and materials.
- 3) Avoids the selection of obsolete (or soon-to-be obsolete) parts and minimizes the selection of sole source and diminishing source parts.
- 4) Avoids the use of unproved technology as much as possible.
- 5) Avoids the selection of parts that are incompatible with existing manufacturing capabilities.
- 6) Avoids unnecessary inventory, resulting in cost increases.
- 7) Avoids unwarranted expansion of sub-tier supplier base and additional costs for surveys.
- 8) Logistics is improved due to the decrease in the number of part types that must be available as spares.

3.7 Typical Microcircuit Parts Selection Flow depicted in Figure 4

Block #1 Market Research establishes a listing of all suppliers who could potentially meet the customer's performance requirements.

Block #2 Customer performance requirements are submitted to potential suppliers to determine their product capability.

- Specific Design Issues may include: (a) Circuit Density, (b) Gate Count, (c) Electrical current densities (d) Ram, (e) Registers (f) Input/Output (I/O) and (g) Delay path performance
 1. Process Capabilities
 2. Quality System
 3. Control of process - SPC
 4. Reliability Program that addresses technology testing
 5. Failure Analysis Support
 6. Test Capability
 7. Packaging Capability
 8. Business & Pricing issues (NRE)

Block #3 Review the preliminary responses from the suppliers and determine which suppliers will most likely be able to meet your performance requirements. If not, continue the market research or consider a custom designed part.

Block #4 The data from the above inquiry for each of the 9 categories is compiled (Pareto chart) into a final rating with specific weighting values based on immediate and projected needs for each of the suppliers.

Block #5 Review the supplier's capability and data available to determine their competence to qualify the part to meet the performance and environmental requirements.

Block #6 If the device offered by the supplier is mature and has been offered for an extended period to customers, the qualification data and the history of product returns including any corrective active reports and failure analysis information should be obtained.

Block #7 Qualification by similarity may be possible when the device is the same as a family of parts previously available and qualified.

Block #8 When the product is of a new technology or involves a major design change, the supplier should submit a qualification plan and perform an evaluation to ascertain whether or not these tests will assure that customer performance and integrity requirements will be met. This

qualification plan should include both the product technology & specific application qualifications. (See note 1)

Block #9 Failure Rate Projection is determined by: (a) calculating (see note 2) the failure units (FIT) for HTOL, Temperature/Humidity and temperature cycle test and correlate results to using reliability requirements, (b) extrapolate life test to actual field temperatures (see note 3), (c) computing the voltage acceleration factors (see note 4), (d) computing the temperature cycling failure rate (plastic devices) (see note 5), and (e) computing the moisture intrusion/corrosion failure rate (plastic devices) (see note 6)

Block #10 Second supplier downselection is conducted.

Block #11 Supplier surveys are conducted as necessary to determine that the proper process controls are in place to ensure delivery of acceptable product.

Block #12 The final supplier(s) downselection is conducted.

Block #13 On-going technical interface with the supplier is maintained. During the product life cycle, it is necessary to determine the product reliability growth and failure analysis from product that is removed from a board or from field returned units. Requalification of the product may be necessary if changes are made to the die attach, die change, encapsulation material, packaging, wirebonding, or processes.

NOTES:

1. CHARACTERIZATION DATA IS USUALLY AVAILABLE FROM THE PRODUCT ENGINEER OR CHIP DESIGNER SHOWING PARAMETRIC CHANGES OVER A WIDE TEMPERATURE RANGE OF OPERATION.

2. FIT = FAILURE UNITS = 1 FAILURE IN 10^9 DEVICE-HOURS = .0001% / 1000 HOURS = .001 PPM

3. ARREHENIUS EQUATION = A.F. $t_1/t_2 = e^{[E_a/kT_1 - E_a/kT_2]}$, where k = Boltzman's constant

4. CROOKE'S EQUATION = A.F. $v_1/v_2 = e^{[\beta(v_1 - v_2)]}$, where $\beta = C/T_{oxide}$, and C = electric field constant

5. COFFIN-MANSON = A.F. $\Delta T_1, \#cycles_1 / \Delta T_2, \#cycles_2 = (\Delta T_{test} / \Delta T_{use})^{-1/b}$, b = accel. exponent

6. PECK'S MODEL = A.F. $T_1, RH_1 / T_2, RH_2 = e^{[E_a/kT]} (RH)^{-B}$, where B = acceleration exponent

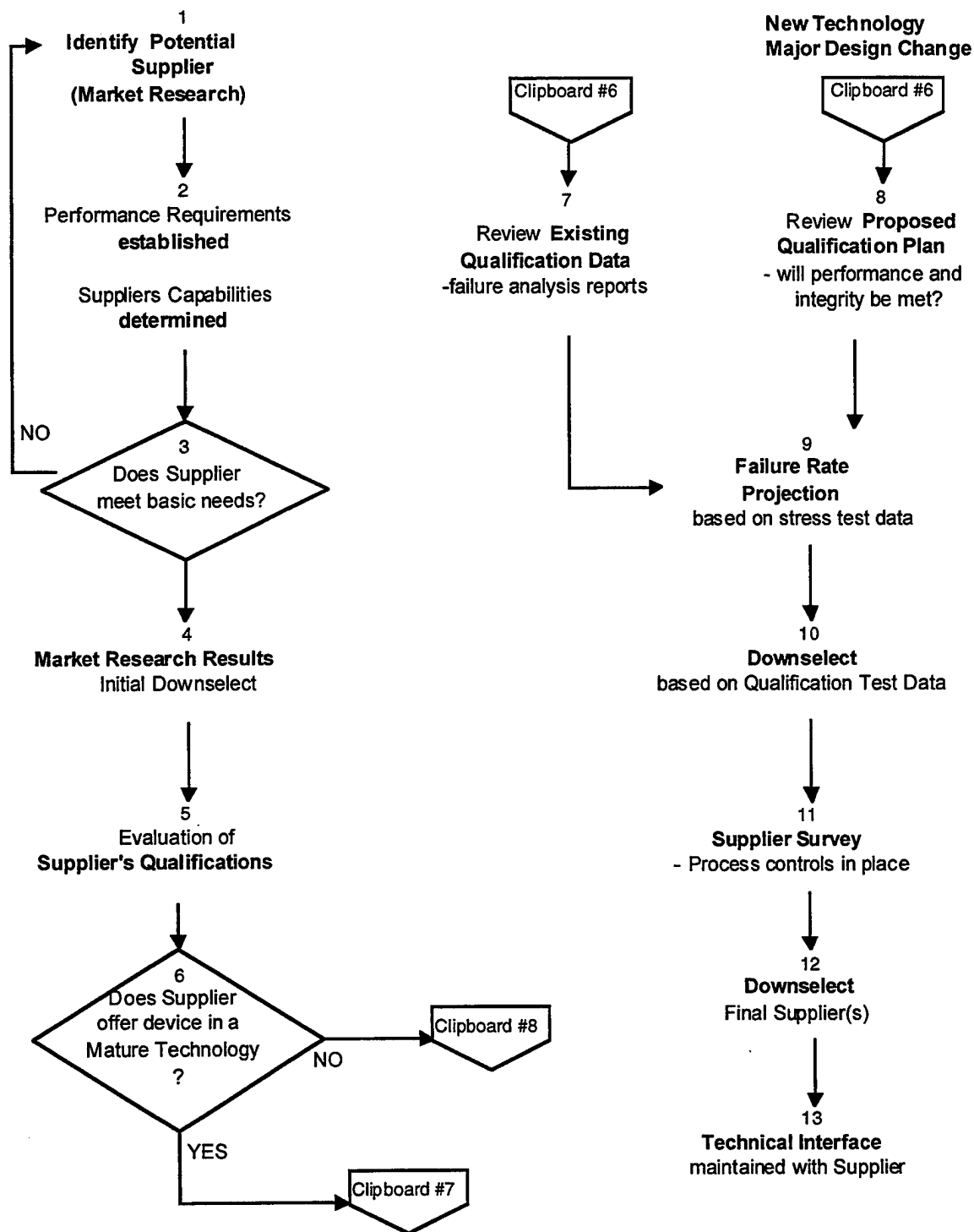


Figure 4. Microcircuit Parts Selection Flow

4. Configuration Management

Objective: To ensure adherence to requirements and product repeatability.

This requirements document was developed with the cooperation of commercial industry and military contractors, to establish the agreed upon "best practices" requirements for Configuration Management (CM). Drawing and specification practices are jointly established between the customer and supplier and are not addressed in this manual.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix⁷⁶. The supplier's own processes or systems must meet the intent of ISO 9002 and these requirements. The requirements for policies and/or procedures are established:

Requirement Title	Par.
1. 4.1 Configuration Management Procedures and Planning	4.1
2. 4.2 Subcontractor Configuration Control.....	4.2
3. 4.3 Configuration Control Board	4.3
4. 4.4 Interface Management.....	4.4
5. 4.7 Part Numbering Controls	4.7
6. Configuration Baseline Management	4.9
7. 4.9 Configuration Change Management.....	4.9
8. 4.9.1 Major Engineering Changes.....	4.9
9. 4.10 Request for Variance (Waiver/Deviation)	4.10
10. 4.11 Configuration Status Accounting.....	4.11
11. 4.12 Disaster Recovery Planning.....	4.12
12. 4.13 Product Serialization	4.12
13. 4.14 As-Built Configuration Report	4.14
14. 4.15.1 Functional Configuration Audits	4.15.1
15. 4.15.2 Physical Configuration Audit	4.15.2

4.1 Configuration Management Procedures and Planning

Definition: Configuration Management consists of procedures for controlling the release, change and use of documents that define the current product baseline and for authorizing necessary actions to be performed to implement changes (routine and emergency) that may affect product during its entire life cycle. The procedures should provide for various necessary approvals, specified points and times for implementing changes, removing obsolete drawings and specifications from work areas, and verification that changes are made at appointed times and places. Configuration management may be performed by multiple suppliers during the product

⁷⁶ Organizational and Technical Interfaces BP Requirements Section 1

life cycle.⁷⁷ Only officially released documents are authorized for procurement, manufacture, test and inspection of the deliverable product.

Document release is the designation by the originating activity that a document, including Engineering Change Notice (ECN) and work authorization, is complete, suitable for use, and subject to configuration change management procedures. Document or computer software release authorizes use of the document or software for any authorized acquisition or build.

RELEASE is performed by the Supplier;

APPROVAL is granted by the customer or document owner.

The supplier shall describe their internal Configuration Management⁷⁸ procedures, processes, and standards to control changes and provide a positive method of ensuring current released documents are available in a timely manner, at appropriate locations, during the product life cycle.

Positive methods for ensuring document approval, release and distribution to appropriate locations (i.e. material planning, purchasing, manufacturing planning, shop floor or inspection) necessitate a 4.3 Configuration Control Board (par. 4.3) or equivalent method for change control (par. 4.9).

4.1.1. Configuration Management Plan

When the supplier's existing configuration management systems and procedures do not adequately address customer requirements, a Configuration Management Plan is developed in sufficient detail by the supplier and provided to the customer. The plan should clearly describe their intended approach for compliance and for compliance by sub-tier suppliers. This Plan may be combined with the overall Program Control Plan.

At a minimum the Configuration Management Plan consists of the following:

- Organization structure⁷⁹ with defined CM roles and responsibilities
- Written summary of applicable policies, procedures, national or industry standards
- Subcontractor configuration control. (par. 4.2)
- Interface management (par. 4.4)
- Configuration identification and baseline control processes (par. 4.5)
- Change controls, review and releasing of documentation (par. 4.9)
- Configuration status accounting (par. 4.11)
- Disaster recovery plan for data and drawings (par. 4.12)
- CM reviews and audits (par. 4.15)

⁷⁷ EIA STANDARD IS-649-95 National Consensus Standard for Configuration Management

⁷⁸ ISO 10007:1995-04-15 Guideline for Configuration Management par. 5.3, 7.4, 7.7

ISO Q9001-1994 par. 4.5.1 Document and Data Control

⁷⁹ See Section 1.0 Organizational and Technical Interfaces

This Configuration Management Plan typically requires customer approval prior to implementation or for any changes affecting the intent of the plan.

4.2 Subcontractor Configuration Control

As the product being purchased becomes more expensive, more complex, or more critical to system performance, the control over subcontractors should be increased to the point that a major subcontract would have the same configuration management requirements as the primary supplier. When tailoring of a subcontractor's existing systems is required, a program control plan should be prepared to explain the extent of their modification and the methods for monitoring the sub-tier supplier's controls.

The supplier shall establish formal Subcontractor Configuration Control⁸⁰ procedures to establish the extent of their control over subcontractors as appropriate to the product being acquired.

CAUTION: The practice of a higher level customer flow down of requirements is NOT a commercial practice and may preclude contracting with a commercial supplier.

If requirements for sub-tier supplier configuration management is mutually agreed upon, the extent of the flowdown should be clearly defined in the contract or statement of objectives and in the supplier's program control plan.

4.3 Configuration Control Board

A Configuration Control Board (CCB) has the authority to review and approve/disapprove the CM plan, CM procedures, the selection of configuration items and configuration baselines and changes to those baselines including product variances approved or changes submitted by the customer.

The supplier shall establish a formal Configuration/Change Control Board⁸¹ (CCB) or equivalent process for the management, review and approval of all changes, internally or externally generated, affecting a baseline, i.e. drawings, specifications, and variances.

It is recommended that a Configuration Control Board be made up of all required technical (design engineer, manufacturing engineering, production control, manufacturing, quality engineer, test engineer) and administrative (program management, purchasing/planner, configuration management) personnel.

⁸⁰ EIA 649-95 par. 5.1.6 Supplier Configuration Management "... when there is a rational need ...as appropriate to the product being acquired."

ISO Q9001-1994 par. 4.6.2 b) "... control exercised ... over subcontractors."

⁸¹ ISO 10007:1995-04-15 par. 3.4, 7.3 Configuration Board
ISO 9001: par. 4.5.3 Document and Data Changes

4.4 Interface Management

Definition: Interface management is the system engineering (or design) process of identifying, recording, and controlling the functional, physical, and performance requirements at common boundaries between two or more interacting pieces of equipment, facilities, and computer software products as defined in the specifications and drawings.

The supplier shall provide for effective management of product interfaces.⁸²

Customer identification of critical interface management criteria is usually accomplished by designation as a special or key characteristic on drawings. The designation of a key characteristic requires the manufacturer to control specified interfaces by the use of Statistical Process Control (SPC) or inspection techniques and data recording per the program control plans. (See Section 10.0 - Process Controls and Appendix B. - Key Characteristics.)

4.5 Selection of Configuration Items

Definition: Configuration identification is the product definition process of documenting the design in the form of drawings, specifications, planning bills, bills of material, product structures, and procedures, naming the items depicted through use of drawing titles and part numbers, and individualizing the parts through identification of serial numbers, lot numbers and/or date codes. Configuration identification of customer designs is not applicable for contract manufacturing requirements.

Definition: A configuration item (or model numbers with designated options) is an aggregation of hardware and software which satisfies an end use function, or any of its discrete portions (sub-assemblies), that is treated as a single entity in the configuration management process. The design agent normally selects configured item designations⁸³ for items controlled by their configuration management process.

The following listing may be used as guidance to determine if a product sub-assembly should be designated as a configured item⁸⁴. One or more of these characteristics may be sufficient to designate a product or sub-assembly as a configured item.

- Functional requirements
- Physical characteristics
- Crucial for successful functionality
- State-of-the-art technology or new design is used in product
- Interface requirements

⁸² ISO 10007:1995-04-15 par. 7.2.1, 7.4.2 ... evaluation of changes ...

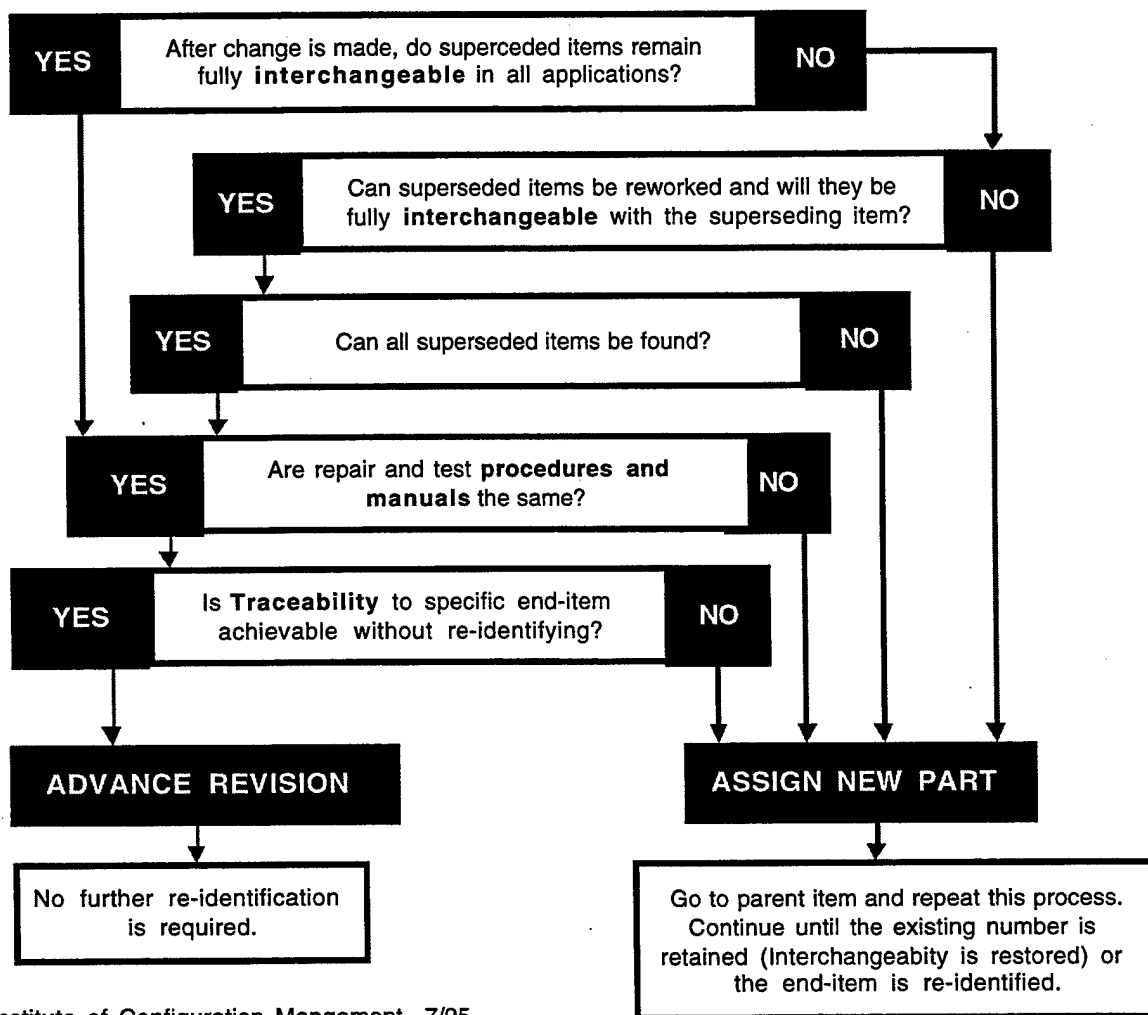
⁸³ ISO 10007:1995-04-15 par. 7.2.1 Selection of Configuration Items

⁸⁴ ISO 10007:1995-04-15 par. 5.2 & 7.2.1

- Make/Buy decisions (procured items/assemblies from different suppliers)
- Logistics and maintenance requirements (spares).
- Scheduling/Phasing (timely manufacturing integration)

4.6 Document Numbering Controls

A single functional organization should assign and control unique identifying numbers⁸⁵ to documents. This discrete identifying number may be determined either by the customer for contract manufacturing requirements or by the design agent for proprietary items provided. Figure 4-1. Part Number Re-identification Tree⁸⁶ illustrates some of the questions that should be answered to determine when a part number should be changed.



Institute of Configuration Management 7/95

Figure 4-1. Part Number Re-identification Tree

⁸⁵ ISO 10007:1995-04-15 par. 5.2.3 & 7.2.3

⁸⁶ Institute of Configuration Management, 7/95 PO Box 5656, Scottsdale, AZ 85261-5656

4.7 Part Numbering Controls

The Part Identification Number⁸⁷ shall be changed whenever a non-interchangeable functional or physical condition is created or when new or revised testing, maintenance, repair, training, operating procedures or manuals, equipment or software is required.

4.8 Configuration Baseline Management

Figure 4-2. Configuration Management Model below illustrates a typical configuration management overview process that is timephased during a product life cycle. The dark symbols indicate CM activities or reports that may be required by the customer. The light shaded areas indicate activities that may involve the customer, specifically with cross-functional teams and with respect to the customer reviews that may be conducted. Configuration baselines are established respectively during product definition, development and production phases of the contract and become major milestones for life-cycle phasing. Configuration baselines define formal departure points for control of future change activity.

The supplier shall establish by mutual agreement with the customer, Configuration Baselines (B/L)⁸⁸ according to the program phase: Requirements B/L, Design Release B/L, Production B/L.

4.8.1 Requirements Baseline

Definition: The Requirements Baseline⁸⁹ specifies the system functional, interoperability, interface, and verification requirements. This may be established by the customer during initial concept or requirements definition phase.

Note: Additional program, design and assembly requirements may be called out in other contractual documentation such as the Contract, Purchase order, program plans, statement of work, milestone and delivery schedules, packing and shipping instructions, traceability requirements, Contractor/Supplier Data Requirements List (C/SDRL), testing and/or validation requirements, State or National regulatory requirements and any other requirements imposed by or developed with the customer during the Quality Functional Deployment (QFD) process or the supplier's self-imposed design rules

⁸⁷ ISO 10007:1995-04-15 par. 5.2.3 & 7.2.3

EIA IS-649-95 par. 5.2.3.d Product Identification

⁸⁸ ISO 10007:1995-04-15 par. 3.3, 5.2.4, 7.2.4, Annex C

EIA IS-649-95 par. 5.2.5 Baselines

⁸⁹ EIA IS-649-95 Pg. 20

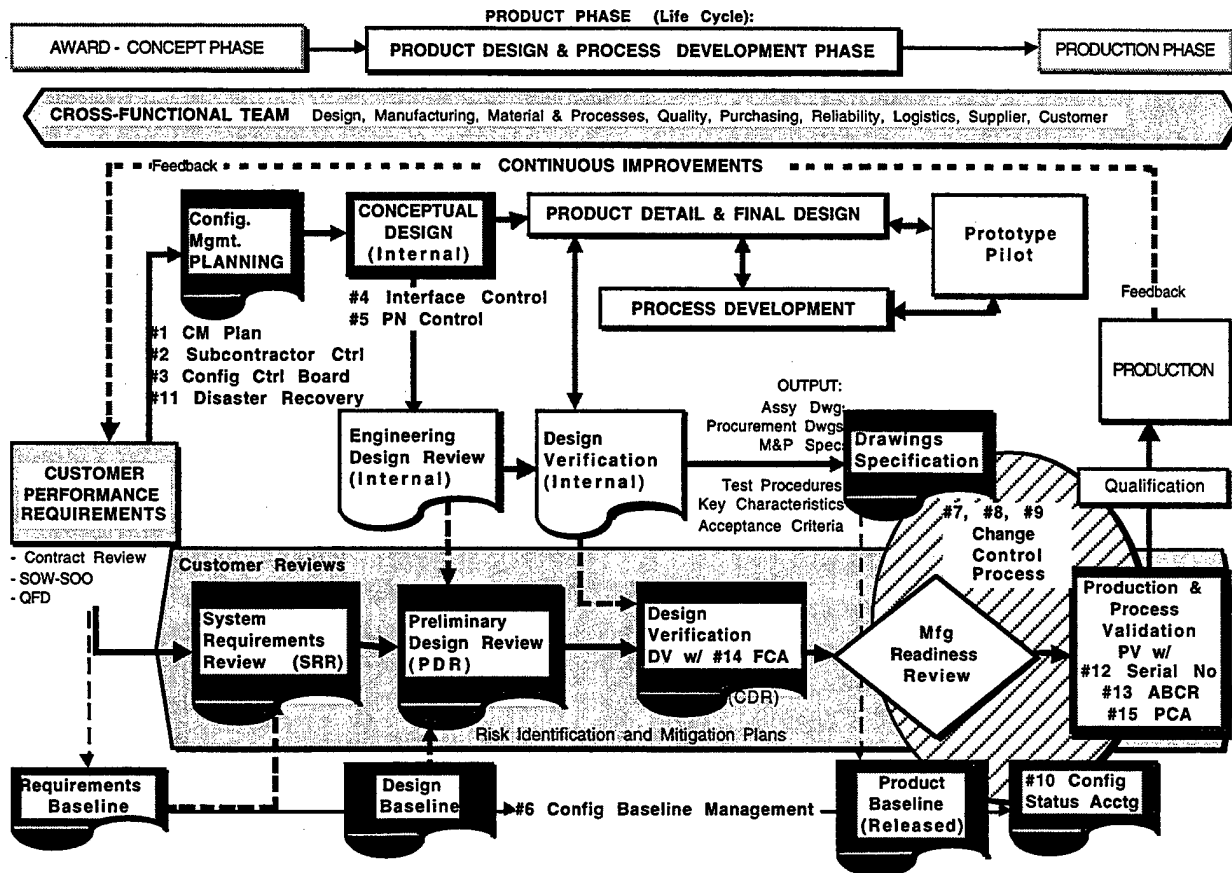


Figure 4-2. Configuration Management Model

4.8.2 Design Release Baseline

Definition: The Design Release Baseline (DRBL) is the initially approved documentation and software describing the requirements Baseline functional, interface and verification requirements. The DRBL configuration is controlled by the supplier with specified customer review points established as a part of the program phasing requirement and is used for configuration audits.

The results of the final design review (Critical Design Review) are incorporated into the specifications and drawings that define the Design Released Baseline. The “approval” of the DRBL constitutes the production release configuration documentation.⁹⁰

4.8.3 Production Baseline

Definition: The Production Baseline⁹¹ (PBL) includes a full set of released “build-to” product documentation that specifies the technical description, physical and functional characteristics, and required acceptance requirements as specified in the Design Released Baseline. The

⁹⁰ ISO 9004 par. 8.6 Design baseline and production release

⁹¹ ISO 10007 Annex C

Production Baseline is established after completion of Production Validation (PV) and becomes the document initiating commitments for tooling and materials, etc.

4.9 Configuration Change Management

All changes or variances to officially released documentation (design documents, specifications, procedures, drawings) shall require review and approval, prior to making document changes,⁹² by the original approving functions or document owner, and authorization by a formal engineering change document.

Document examples include, but are not limited to: Engineering Order (EO), Engineering Change Notice (ECN), Document Change Notice (DCN), Engineering Change Order (ECO), Show Variance (SHOVAR).

Engineering change documents should contain the following.

- Unique document identifier
- Name and organization of requester
- Description of change or variance
- Class of change (major or minor)
- Reason for change
- Cost implications of change or variance
- Listing of documents to be revised or components affected
- Urgency or desired effectivity (or cut-in point)
- Evaluation and approval of change by CCB and customer if applicable.
- Corrective action to prevent recurrence (variances only)

4.9.1 Major Engineering Changes

Definition: A major (Class 1) change constitutes a formal change to the current baselined configuration documentation which has significant impact on the key characteristics (form, fit, function, interface) of the product, and requires coordination, review, and approval.

The following major engineering change examples that may be applicable:

- Interface characteristics
- Interchangeability, substitutability or replaceability
- Compatibility with other equipment or software
- Performance
- Reliability, maintainability or survivability

⁹² ISO Q9001-1994 par. 4.5.3 Document and Data Changes
ISO 10007:1995-04-15 par. 7.4

- Electromagnetic characteristics
- Weight, balance or moment of inertia
- Sources for configured items defined by source-control drawings
- Safety
- Customer furnished equipment
- Operation and maintenance manuals
- Preset adjustments affecting operations
- Skills, manning, training or other human-engineering requirements

All Major (Class I) changes, including those proposed by supplier/subcontractors, shall require formal communication with the customer or drawing owner using the supplier's own form and written approval by a designated approval authority⁹³.

The degree of change formality may vary during the development phase and prior to Critical Design Review, depending on the customer's involvement during this phase. For proprietary designs, impact on form, fit, function, performance, and/or durability should be determined with the customer so that all effects on the product can be properly evaluated. Full or limited re-qualification testing may be required to ensure the product performance, form, fit, function, durability, and reliability requirements are still met under the new configuration. *Note:* The Government customer may require a DD Form 1692 for Engineering Change Proposals for Class I changes.

4.9.2 Minor Engineering Changes

Definition: Minor (Class 2) changes are applicable during the production phase and are normally identified and processed to correct documentation errors or to enhance contractor producibility without changing the customer-approved configuration. Minor changes affect only the design release and product configuration baseline. A minor change does not affect interchangeability and does not affect customer requirements.

Minor engineering change examples include substitution of parts which do not impact function, logistic or reliability and documentation changes (record changes, correct errors or add notes).

⁹³ EIA IS-649-95 Pg. 26, 5.3 (b) Change Management; 5.3.1.2 (a) Major ISO 10007:1995-04-15 par. 7.4

4.10 Request for Variance (Waiver/Deviation)

Definition: A variance is a temporary departure from the baseline requirements and does not anticipate a revision of the applicable requirement document or configuration documentation.

When a known departure from requirements is incorporated, the supplier shall document a Request for Variance and obtain appropriate authorization.⁹⁴

4.11 Configuration Status Accounting

A Configuration Status Accounting (CSA) report contains all customer released drawing revision/change status at time of build/assembly.

The supplier shall maintain a Configuration Status Record⁹⁵ with contents mutually defined as indicated in the contract and Program Control Plan.

A typical Configuration Status Record includes the following at a minimum:

- Configuration baseline documents
- List of configuration items and identification numbers
- Current approved revision status of documents
- Status of proposed engineering changes
- Status of variances (waivers and deviations)
- Effectivity date or date of implementation in production
- Releasing authority
- Results of configuration audits (As-Built vs. As-Designed)
- Configuration of units in operational inventory (post-delivery), when required by contract or statement of work
- Other customer-specified data elements

4.12 Disaster Recovery Planning

The recovery plan for electronic data requires frequent and regular backups for production critical data files and storage in a separate location.

⁹⁴ ISO 10007:1995-04-15 par. 7.3, 7.5.2

EIA IS-649-95 Pg. 34, par. 5.3.4

⁹⁵ ISO 10007:1995-04-15 par. 7.5.3 CSA Reporting
EIA IS-649-95 Pg. 34, par. 5.4

The supplier shall have an effective Disaster Recovery Plan⁹⁶ and process in place to enable reproduction of both historical and current documents and data including supplier-generated documents and data for the product design, production & test in the event of potential destruction by fire, flood, theft or other forms of loss.

4.13 Product Serialization

A serial/lot number and/or supplier identification number shall be assigned to each Model number or Configuration Item (CI) unit for the purposes of control, traceability⁹⁷ and customer acceptance.

4.14 As-Built Configuration Report

The As-Built Configuration report (ABCR) indicates the number of units that are produced to a specified configuration and/or the applicable serial number range. This listing is taken from production documentation (shop orders or computer-integrated-manufacturing systems, drawings, revisions, components and materials) that were used for each assembly or lot.

The supplier shall provide an As-Built Configuration Report⁹⁸ with contents as defined in the contract and Program Control Plan, to verify that all Major (Class I) changes were incorporated into the product and to indicate approved variances.

Typical ABCR report headings include the following.

- Part number: an indentured listing of assembly, subassembly, part number (including substitute and alternate part numbers)
- Part description
- Latest released revision or change
- Reference designator location where part is installed
- Quantity produced in lot or batch.
- Traceability information: component/material supplier name or number, lot/date Code or serial number

4.15 Configuration Reviews and Audit/Verifications

Configuration reviews, Functional Configuration Audits (FCA) and Physical Configuration Audit/Verifications (PCA) should be documented in the Configuration Management Plan⁹⁹. Early involvement of the customer, or their representative, and sub-tier suppliers in the cross-functional development team is key to successful product development, improvements in the time-to-market and assurance that transition to production will be as smooth as possible. The

⁹⁶ ISO 10007:1995-04-15 par. 5.3 Configuration Control - disaster recovery

⁹⁷ ISO 9001 Quality Systems Model par. 4.8 Product Identification and Traceability

EIA IS-649-95 par. 5.2.3.1 Identifying individual units

⁹⁸ ISO 10007:1995-04-15 par. 7.6 Configuration audit procedure "as built/produced"

EIA IS-649-95 Pg. 38, par. 5.5 Figure 12

MIL-STD-973 App. H Task 501 pg. 199

⁹⁹ Section 1.0 Organizational and Technical Interfaces, par. 1.4

cross-functional teams should include representatives with authority to accept the progress during these reviews. Periodic cross-functional team technical interchange meetings (TIM) should be held to review design or development progress.

There are two distinct opportunities for configuration reviews

- The supplier has responsibility for product design, the customer may conduct a Functional Configuration Audit (par. 4.15.1) at Design Verification to ensure the design will meet their requirements. (See Section 2.9 Design Reviews)
- The supplier has no design responsibility but is responsible for product assembly or manufacturing in compliance with a Build-To-Print (BTP) technical data package provided by the customer. The customer may conduct a Physical Configuration Audit (par. 4.15.2) at Production Validation or Production Readiness Review to ensure that the first piece from production will meet the design documentation.

When the design facility and production facility are the same organization, it is preferable the FCA and PCA reviews be conducted separately at the Critical Design Review (CDR) and at the Production Readiness Review (PRR) review respectively. However, it is possible for the FCA and PCA to be conducted simultaneously at the PRR. When FCA is delayed to PRR, there is a risk assumed by both supplier and customer that the product may not meet requirements and the customer's system schedules can be adversely affected by production slippage.

Generally configuration reviews and verifications consist of two types.

4.15.1 Functional Configuration Audits

Definition: Functional Configuration Audits include a documented examination of preproduction development units where tests and/or analysis of data verify that the design has achieved the functional, physical, and performance requirements specified in the Design Released Baseline documentation and is capable of being produced. The product baseline is thereby established upon FCA acceptance by the customer.

At the completion of product development, the design agent shall conduct a formal design verification Functional Configuration Audit¹⁰⁰, verifying the customer requirements against the Design Released Baseline. A design Certificate of Compliance shall be submitted by the design agent, which affirms that the design meets customer's Form, Fit, Function & Interface requirements.

FCA is the most critical of the two configuration reviews and is accomplished during multi-functional team design review meetings. These reviews require extensive support from the product design team and the configuration management functional organization and should include customer involvement when appropriate. At the completion of the design activity, the design

¹⁰⁰ ISO 10007:1995-04-15 par. 7.6 Configuration Audit Procedures
ISO 9004 par. 8.5.3 Design Verification

activity product manager (or cross-functional team lead) has primary responsibility for Functional Configuration Audits.

A process to trace design attributes to customer requirements should be developed and maintained during these reviews and subsequently provided to the customer for facilitation of their final design review. This may include a relational database or a manual listing of customer requirements to design attributes. Critical processes affecting key characteristics (product or process) should be identified and provided to the customer.

At the conclusion of each phase of design development, a formal, documented, systematic and critical review of design results should be conducted to verify that the product design meets customer form, fit, function and interface requirements. The cross-functional examination includes adequate documentation of test and/or analysis data from engineering tests and analysis of similar product, simulations or models are used to demonstrate that manufacturing processes are in control and will produce an acceptable product. All activities, design audits, experiments and test results, parts selections, action items, and close-out or corrective actions shall be adequately documented and maintained as agreed. (See Section 2.9 and 5.8)

4.15.2 Physical Configuration Audit

Definition: A Physical Configuration Audit¹⁰¹ (PCA) is a review of the as-built configuration conducted prior to production to ensure the product conforms to its released product baseline configuration documentation.

Definition: Production Validation is the supplier's engineering tests that validate that products made from production tools and processes meet customer requirements and the supplier engineering and manufacturing standards.

The supplier's cross-functional team shall conduct a physical product examination¹⁰² of the first production unit's "as built" configuration against its technical documentation prior to production of contract quantities. The extent of customer involvement is documented in the Program Control Plan.

A product certificate of conformance is required with first article inspections, production readiness reviews, or initial production validations, as applicable.

Physical Configuration Audit (PCA) is accomplished immediately prior to production. Pre-production units or "first articles" are examined against the released design documentation to ensure that the processes and tools used in production will provide an acceptable product. This review may consist of a complete "tear-down" or "layout"¹⁰³ inspection of pre-production validation units with a physical comparison to each drawing and comparison of the test results

ISO 10007:1995-04-15 par. 7.6

¹⁰² ISO 10007:1995-04-15 par. 7.6

¹⁰³ QS-9000 par. 4.10.4, pg. 34, Final Inspection and Testing. "A layout inspection and a functional verification (to applicable customer engineering material and performance standards) is required for all product at a frequency established by the customer. Results shall be available for customer review upon request."

with the requirements or it may simply consist of a certification that the product was built and tested according to the documentation provided. A tear-down inspection is usually inappropriate for expensive product. This examination may be witnessed by the customer when specified in the contract.

The design Functional Configuration audit must have been previously completed or is being completed concurrently with the PCA. PCA is not required on subsequent shipments unless there is a configuration or process change that affects the product form, fit, function and interface.

PCA Submission Requirements

Table 4-1. PCA Submission Level is provided for reference only to assist in determining the basis for appropriate sample and data submission level.¹⁰⁴

- Supplier's quality status (i.e. ISO-9000, Strategic relationship)
- Experience with prior products from this supplier
- Past quality and delivery performance
- Product complexity
- Part criticality to overall system performance
- Supplier expertise with the product or commodity

PCA LEVEL Type of Product	C-of-C Warrant Req'd	PRODUCT SAMPLES Req'd	PCA SUPPORTING DATA Req'd	Submit Samples & Data to customer OR Witness by customer
1) Commodity product or Service Low complexity	Yes	No	None - (Data Retained by Supplier)	Submit C-of-C only for ALL Shipment
2) Manufacturing Service Medium complexity	Yes	No	Limited Dimensional & Test data	Submit Samples & Data to customer
3) Manufacturing Service High complexity	Yes	No	Complete data	WITNESS at PRR or PV Or customer is included in cross-functional team review.
4) Design & Build	Yes	Yes	Limited data - As agreed	Submit Samples & Data to customer
5) Design & Build (Automotive default)	Yes	Yes	Complete data	Review Samples & Data at supplier's location
6) Design & Build High cost product	Yes	No	Complete data	WITNESS at CDR & PRR or PV. Or customer is included in cross-functional team.

Table 4-1. PCA Submission Level

¹⁰⁴ Based on Automotive Production Part Approval Process (PPAP) Submission Levels, pg. 4

Note: Level 5: In the automotive industry product samples and complete supporting data are reviewed by the customer at the supplier's manufacturing location for approval prior to beginning production. Production part approval is granted for a part number, engineering change level, manufacturing location, material subcontractor(s) and production process environment. Change to any of these requires customer notification and possible re-submission of product and data.¹⁰⁵

Production Validation or First Article Review

References: Section 2.0 par. 2.9.5 through 2.9.7, Quality System par. 5.6.2 through 5.6.1.5, and Appendix B- Key Characteristics.

PCA is a Production/Assembly Product Manager's¹⁰⁶ primary responsibility. These periodic reviews will require extensive support from the product team or cross-functional team configuration management, manufacturing and quality assurance functional organizations. Reviews should include a customer witnesses who has the authority to accept the production readiness progress.

The production team should provide the following items for the Production Validation or First Article Review.

- Documentation of critical manufacturing product or process operations affecting key characteristics.
- All summary of production activities, experiments and test results, parts replacements, process performance results and corrective actions that occurred during development.
- Comparison and analysis of the As-Built Configuration Report (par. 4.14) with the Configuration Status Accounting report (par. 4.11), detailing all variances noted with determination of root cause and corrective action taken to ensure the latest released engineering revisions are incorporated into the product and that no unapproved substitute or alternate parts have been used.
- Inspection and test results and supplier's workmanship for initial production validation (PV) samples should be physically compared to released production documentation. During the determination of the supporting data to be provided, remember that the more reports or information provided to the customer the less customer involvement will be required. This supporting data should indicate that processes, controls, and products are functioning properly

Manufacturing Process Control Reports

Key Characteristics Control (See Section 10.4, 10.8 and Appendix B)

¹⁰⁵ QS-9000 Production Part Approval Process pg. 52

¹⁰⁶ NOTE Automotive: Production Part Approval Process (PPAP) is a Quality Engineering function in many automotive companies, not a Configuration Management function. The quality engineer and product manager are responsible for collection of supporting data and submission to the customer (as required).

Key Characteristic reports, in the supplier's format, will be prepared to show compliance with key characteristics contained in customer drawings. For processes affecting a key characteristic, this compliance data may be in the form of SPC records. If no key characteristics are defined, no report is necessary.

Process Performance Results (SPC) (See Section 10.4)

Key processes should be under statistical process control. A summary report, in the supplier's format, depicting SPC results for the period of time that this product was produced, will be provided with physical configuration audit supporting data. This summary report will include an analysis of all points where the process exceeds the Upper or Lower Control Limits and an explanation of the cause and corrective action taken and possible product impact. If no control anomalies were recorded, it will be so stated in the certification of conformance.

4.16 Certification Form

Certification forms may be required for a variety of reasons and depending on customer requirements, this information may be summarized for presentation to the customer, retained by the supplier for a specified period, or provided to the customer with the product. The Certificate of Compliance may be in the supplier's format when the contents meet the intent of the suggested format in the attachment. The form shown at 0 is offered as a possible combination for these two purposes. Two certifications required in configuration management are explained in par. 4.15.1 and 4.15.2.

4.16.1 Certification of Compliance

A Certification of Compliance by the design agent affirms that the design meets customer's form, fit, function and Interface requirements. The Certificate of Compliance is signed by the design cross-functional team representatives or product manager and, ideally, by the team's customer representative thus eliminating the need for further configuration review. Supporting tests or analyses conducted are specified. Customer acceptance of design documentation constitutes production release documentation.

4.16.2 Certificate of Conformance

A Certificate of Conformance is required with first article inspections, production readiness reviews, or initial production validations. The Certificate-of-Conformance certifies that the product is built according to design documentation and specifies supporting tests or analyses that were conducted. The form is signed by the design cross-functional team representatives, product manager, quality manager and ideally by the team's customer representative thus eliminating the need for further physical configuration review. A Certificate of Conformance is the only documentation required for each subsequent shipment unless there is a configuration or process change that affects the product form, fit, function, or interface.

4.17 References

The following first tier non-government standards were reviewed during the development of these configuration control requirements.

- Electronic Industries Association Engineering Department
EIA Interim Standard 649-95: National Consensus Standard for Configuration Management, Draft dated 4/21/95 was used for this document.
- International Standards Organization ISO-10007 Quality Management - Guidelines for Configuration Management, Dated 4-15-95
- American National Standards/ American Society for Quality Control Standards
ANSI/ASQC 9001-1994 Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing. ("ISO" used for brevity.)
- Institute of Configuration Management, Scottsdale, AZ 85261-5656
Tel: (602) 998-8600

Table 4-2. Requirements Analysis Matrix is provided as a cross-reference to the various national and military standards which influenced these Business Practice Requirements.

NOTE: MIL-STD-480, 483 & 1456 have been replaced by MIL-STD-973 (7/17/92).

Requirement	ISO 10007	EIA 649 Draft 4/95	ISO 9001	MIL-STD.
Config. Mgmt Procedures	7.4	5.1	4.4.1	973, 483
CM Plan	7.7	5.1.2	4.2,4.5.1	973, 483
Disaster Recovery Plan	5.3	-	-	1456
Subcontractor CMP	-	5.1.6	-	973, 483
Config Control Board	3.4, 7.3	5.3.2.1	4.4.9	973
Interface Control	5.2.1	-	-	973
Select. Config. Item	7.2.1	5.2	-	480, 483
Document Numbering	5.2.3, 7.2.3	5.2.4	-	973
Part Numbering	-	5.2.3	-	973
Serialization	-	5.2.3.1	4.8	-
Program Phasing	3.3, 7.2.4	5.2.5	-	973, 483
Requirement B/L	-	5.2.5.2a	-	-
Design Release B/L	-	5.2.5.2b	ISO 9004, 8.6	480, 483
Production B/L	Annex C	5.2.5.2c	-	973, 483
Major Changes	7.4	5.3.1.2a	4.4.9, 4.5.3	973, 483
Minor Changes	-	5.3.1.2b	-	973, 483
Waivers/Deviations	7.3, 7.5.2	5.3.4	-	973, 483
Config. Status Acct.	7.5 (all)	5.4	4.5.2	973, 483
As Built Reporting	7.6	5.4.1	-	973, 483
Functional Config Audit	7.6	5.5.2	-	973, 483
Physical Config Audit	7.6	5.5.2	-	973

Table 4-2. Requirements Analysis Matrix

Table 4-3. Production Part Approval contains a comparison of the requirements for approval of production parts for a typical military program where the customer owns the design, an automotive product where the supplier owns the design, and a dual-use Build-to-Print (BTP) program. The column BTP is recommended for use with commercial item subcontracts.

Line	CONFIGURATION AUDIT REQUIREMENT	BTP REQ.	Typical DEFENSE	AUTOMOTIVE
DESIGN RESPONSIBILITY ONLY				
1)	WHEN is DESIGN review conducted? Functional Configuration Audit	@ CDR	Design Reviews @ CDR	Design Eng. approval
2)	Requirements Traceability Matrix Customer "shall" compared to Design Specs		YES	NA
3)	TEST RESULTS - Material, FMEA, performance, durability.	DOE		YES
4)	Certificate of Compliance	YES		YES
Typical PRODUCTION Requirement (No Design activity)				
5)	WHEN is PRODUCTION review? Physical Configuration Verification PCA Submission Level	@ PV Level 3 (pg. 80)	Prior to Production After Qualification test & Acceptance Testing	Production Validation prior to 1st shipment Req'd each Model Yr.
6)	DOCUMENTATION (See Below)	- - -	Full Design Disclosure	ALL design records
7)	a) Part Drawings (Released)		YES - Level 3 Dwgs	YES
8)	b) Specifications (Released)		YES	YES
9)	c) Detail Drawings (Released)		YES	YES
10)	d) Configuration Status Account	YES	YES	NA
11)	e) CAD/CAM math data		NA	YES
12)	f) Action items and Closure		YES	NA
13)	g) As-Built Configuration Report	YES	NA	NA
14)	h) Acceptance Test Procedure		YES	NA
15)	i) Engineering Changes	ABCR	Included above	YES
16)	SAMPLES - Submitted to customer with supporting data	NO	Completed assembly & individual piece parts	Typical: 2 per 300 pcs. lot submitted
17)	PCA SUPPORTING DATA:	- - -		
18)	j) Dimension Verification		YES	Dimensional results referenced to Dwgs
19)	k) Inspection & Test Aides		NA	Checking fixtures
20)	l) Key Characteristic Control	YES	NA	YES
21)	m) Acceptance Test Report	ICT/Final	YES	NA
22)	n) Process Flow Charts		NA	YES
23)	o) Process FMEA		NA	YES
24)	p) Process performance result supporting data	YES	NA	YES
25)	Certificate of Conformance to Design Drawings	YES	Certificate of Compliance signed by QA/Product Mgr.	Warrant document signed by QA Mgr.
26)	REVIEW BY CUSTOMER	NO	YES	Level 5 & 6 ONLY (pg. 80)

Table 4-3. Production Part Approval Processes

4.18 Certification Form

Part Number: _____ Part Name: _____
Released Engineering Drawing Change Level: _____ Dated: _____
Customer: _____
Contract/Purchase Order No./Statement of Objectives: _____ Dated/CN: _____
Supplier Name: _____
Address: _____
City: _____ ST. _____ ZIP: _____

Check all applicable areas - Attached [A] Retained [R] Not Required [NR]

☐ **DESIGN CERTIFICATE of COMPLIANCE**

- ☐ Initial Design (Functional Config. Audit) ☐ Engineering Changes
☐ Test data or analysis results ☐ Pre-production samples
☐ Tests and analyses which demonstrate compliance with requirements are:
[A] [R] [NR] Design reviews have been conducted ☐ with **customer participation**.
[A] [R] [NR] Requirements Traceability Matrix or Table
[A] [R] [NR] Design of Experiments
[A] [R] [NR] Key Characteristics verification
[A] [R] [NR] Analysis by Simulation
[A] [R] [NR] Comparison w/ existing design
[A] [R] [NR] Performance or Durability Tests
[A] [R] [NR] Calculations
[A] [R] [NR] Production feasibility and compatibility studies
[A] [R] [NR] Performance Qualification test under operating conditions.

☐ **MANUFACTURING/ASSEMBLY CERTIFICATE of CONFORMANCE**

☐ **Initial build ONLY** - Production Readiness Reviews:

(Production Validation, First Article Inspection, Physical Configuration Audit/Verification).

Reports or test results which demonstrate conformance to design are:

- [A] [R] [NR] Production Readiness Review completed ☐ with **customer participation**.
[A] [R] [NR] As-Built-Configuration
[A] [R] [NR] Key Characteristic control
[A] [R] [NR] Process performance (SPC) data
[A] [R] [NR] Internal Inspection results: ☐ first-article ☐ in-process ☐ final inspection
[A] [R] [NR] Acceptance Test data
[A] [R] [NR] Final acceptance ☐ data ☐ report

☐ **Changes** to customer pre-approved:

- ☐ Materials ☐ Sub-tier Supplier ☐ Mfg./Assy Location ☐ Mfg./Assy Process
☐ **All shipments:** Number of parts _____ Serial No./Lot #: _____ to _____
☐ Product **variances/deviations** are noted on attached documents.
☐ Product is submitted in full compliance with customer requirements.

☐ I affirm that this **released design** is in compliance with customer Form, Fit, Function and Interface requirements as stated in above contract, Statement of Objectives and statutory & regulatory requirements.

☐ I affirm that **product** represented by this certification has been made to customer drawings and specifications and program control plan, as applicable.

Responsible Manager or designee Date: _____

☐ **SEE ADDITIONAL INFORMATION ON REVERSE SIDE**

5. Quality Systems

Objective: To provide for continuous improvement and variability reduction.

This requirements document was developed with the cooperation of commercial industry, defense customers and contractors to establish agreed upon requirements for Quality System practices. These Quality System requirements are based on ISO Q9001 and ISO Q9004-1-1994 and best competitive practices. These requirements do not intend to specify a national standard, but allow the supplier to select any national standard or develop his own methods, as long as they "meet the intent" of all customer and the Business Practices Manual Requirements.

Definition: A Quality System consists of established, documented and maintained, facility-wide procedures and processes that emphasize product conformance to requirements, defect prevention and variability reduction in an atmosphere of continuous evaluation and improvement during a product life cycle to achieve the highest levels of customer satisfaction.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix. The supplier's own systems or processes must meet the intent of ISO 9001 or ISO 9002 and these requirements. The requirements for policies and/or procedures are shown below.

Requirement Title	Par.
1. 5.4 Quality System Documentation.....	5.4
2. 5.5.2 Initial Lot Validation	5.5.2
3. 5.5.3 In-process Inspections	5.5.3
4. 5.5.4 Final Inspection.....	5.5.4
5. 5.5.5 Customer Witness of Final Acceptance	5.5.5
6. 5.6 Nonconforming Product Determination Authority	5.6
7. 5.7.1 Record Retention.....	5.7.1
8. 5.8 Continuous Improvement.....	5.8
9. 5.9 Cost-of-Quality	5.9

5.1 Risks Influence Government Requirements

The application of additional product performance requirements and supplier controls to a contract, is associated with the level of the Government's risk assumed. The more risk assumed by the government, the more control requirements and oversight are required of the supplier. These risks include (but are not limited to) complexity of the product, past performance of suppliers and maturity of the product.

The most effective risk mitigation approach is a firm-fixed price Commercial Item acquisition. Commercial items should not require additional quality system requirements, testing, or supplier certifications,¹⁰⁷ unless the existing product data or past performance information is insufficient. However, the government reserves the right to require proof of conformance to the supplier's specifications.

5.2 Basic Quality System Model

This basic quality system model is equivalent to or meets the intent of the requirements contained in ISO Q9001-1994 or ISO Q9002-1994. These elements represent the minimum management infrastructure processes required for non-complex products. The International Organization for Standardization: ISO Q9001-1994 Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing contains 20 elements including requirements for a Company Policy, Quality Manual and 18 documented procedures and 16 reporting requirements. This standard is used for suppliers with design and development responsibility and is used as the basis for various sections of the Business Practices Manual requirements.

ISO Q9002-1994 Quality System Model for Quality Assurance in Production, Installation, and Servicing is used for the "build-to-print" contract with no design or development activity. Q9002 requirements are the same as Q9001, except for Section 4 Design Controls.

The supplier of low value, non-complex product or commercial-off-the-shelf (COTS), or other commercial items or nondevelopmental products may not be required to demonstrate an "approved" quality system. Such a supplier has established an acceptable quality program and performance history as indicated by customer (market) acceptance of its' product. As the product complexity and supplier responsibility increases, suppliers must become compliant with these basic quality system requirements to be approved for procurements. When the product is "build-to-print," complex, high value or critical to system performance the customer may require additional implementation of advanced best practices.

When there is no previous experience with a supplier's product, performance or capability the basic quality system model, Figure 5-1 below, illustrates the level of detail for an initial evaluation for new suppliers where more emphasis on documentation Levels I (Policies), II (Procedures), and III (Process instructions) are required to ensure the supplier has the proper procedures, processes and controls in place.

- Level I documentation typically includes (a) mission statement, (b) objectives, scope, and approach,[JRM168] (c) responsibility and authority for implementation, maintenance and auditing.

¹⁰⁷ Memorandum for Standardization Management Activities, Commercial Item Description May 2, 1996

- Level II documentation typically includes the quality manual and internal procedures.
- Level III documentation typically includes Process Control Plans and process instructions.
- Level IV documentation typically includes (a) continuous improvement program and reduction of product variations and (b) product qualification results and test data.

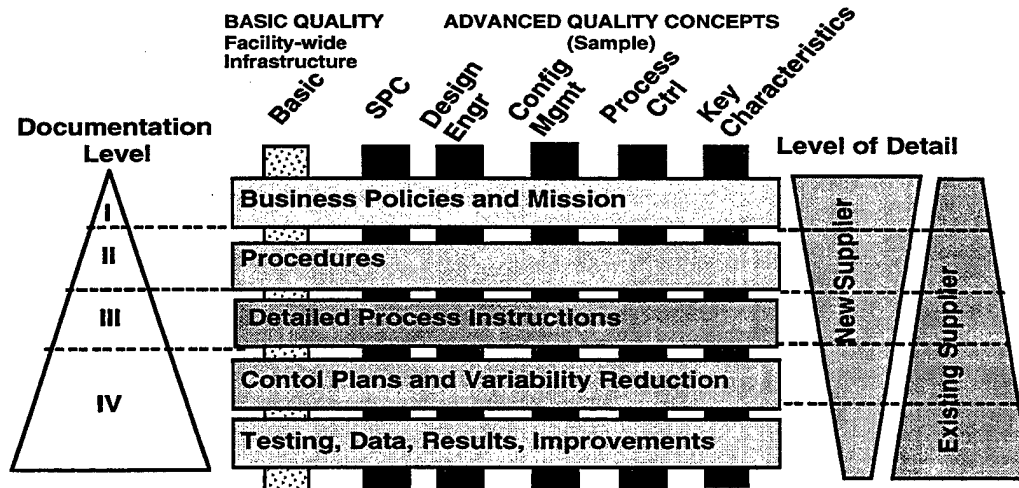
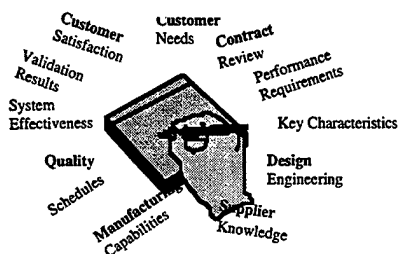


Figure 5-1. Quality System Model

Until new suppliers prove their capability to control the process and provide acceptable product, customers may require more in-house witnessing or verifications of controls. As experience with a supplier increases, as shown in the existing supplier level of detail bar on the right, the customer oversight should be reduced and shifts to reviews of the supplier Level IV documentation and advanced best practices such as Control Plans, process controls, variability reduction efforts, and product test data. All ISO-certified suppliers are required to conduct an annual self-assessment for ISO registration and a customer may require a copy of any self-assessments that have been conducted.¹⁰⁸

5.3 Advanced Best Practices



Advanced best Practices provide for a team focus on conformance to requirements, robust design practices, production processes, defect prevention and variability reduction in products and processes through highly developed and sophisticated controls.

These best competitive practices have been adopted by many suppliers as company standard practice. The Original Equipment Manufacturers (OEM) or defense customers frequently require a variety of these practices to cement a higher level

¹⁰⁸ TRW Automotive Supplier Development Manual, pg. II-3

customer-supplier relationship. OEMs such as: Boeing - D1-9000¹⁰⁹, Ford - Q1, automotive industry - QS-9000, and McDonnell Douglas - "Gold, Silver, Bronze Supplier Certification" are examples of these practices.

Advanced Best Practices may require tailoring of existing processes to meet customer requirements, depending on the complexity and criticality of the product, the degree of documentation required and the extent of flow down to subcontractors. Hence, the requirements for Advanced Best Practices are usually specified in the Contract or Statement Of Objectives (SOO) and are usually agreed upon prior to final contract negotiations.

5.4 Quality System Documentation and Planning

The supplier shall describe their facility-wide Quality System meeting the intent of ISO Q9001-1994¹¹⁰ or ISO Q9002-1994 as indicated in the contract and Statement of Objectives.

5.4.1 Quality System Plan

When the supplier's existing quality systems and procedures do not adequately address a customer's requirements, a quality plan is developed in sufficient detail and provided to the customer. The objective of this plan is to clearly describe the supplier's quality organization¹¹¹ and the intended approach for compliance of the supplier's and sub-tier supplier's Quality Systems with the customer's requirements. The plan may be combined into an overall Program Control Plan. This quality plan typically requires customer approval prior to implementation or for changes affecting the intent of the plan.

The quality plan consists, at a minimum, of the organization structure with defined roles and responsibilities and written summary (listing) of applicable policies and procedures, and industry standards being used.

5.5 Inspection and Testing

The customer required inspection and testing are documented in the supplier's quality procedures.¹¹² Special customer required inspections or tests are documented in a control plan.

¹⁰⁹ Boeing DI-9000 Advanced Quality Systems for Boeing Suppliers®

¹¹⁰ ISO Q9001-1994 Par. 4.2.2 Quality System Procedures

¹¹¹ See Section 1.0 Organizational and Technical Interfaces

¹¹² ISO Q9001-1994 Par. 4.10 Inspection and Testing

5.5.1 Customer Surveillance and Inspection



The supplier is required to have procedures for receiving inspection, In-process inspection and testing, and final inspection and testing. In addition, ISO provides for customer verification of product at both the supplier's and subcontractors¹¹³ facilities. Customers are permitted to witness the inspection and testing, particularly for new products. This is usually accomplished during the Production Validation (PV) phase.

The defense customer delegates both surveillance and inspection at supplier and subcontractor locations to their representative, the Defense Contract Management Command (DCMC). The current DoD source inspection philosophy is to reduce source inspection when product complexity is minimal or when the supplier's existing data, past performance and quality records warrant such a decision. On-going customer surveillance (insight) of the manufacturing processes should be used in lieu of inspections.

CAUTION: The defense customer reserves the right to inspect at the supplier when acquisition of complex products, problems in past quality or delivery performance, or customer reviews indicates a need for final acceptance at the supplier.

When customer surveillance is required in the contract, the supplier and customer mutually establish a Program Control Plan for customer participation in design reviews and verification, product validation, or inspections prior to production release.

5.5.1.1 Commercial Items

Product quality of commercial items¹¹⁴ may be documented using historical market satisfaction or process and test yield data; therefore, no additional inspection or quality systems are required.

5.5.2 Initial Lot Validation

First article validation for initial builds of complex or critical products may be required by the defense customer to verify conformance with the product requirements prior to the initial production build (Production Validation phase). "First articles" must be representative of the production runs and may include initial production samples, first lot, pilot models or other samples as mutually agreed upon. First article inspection (production validation) does not usually include the customer and may not impede the production flow. The requirement below is added to include the customer or their representative's participation as a witness of the first article inspections and testing by the supplier. (See Section 2.0 - Design Controls)

¹¹³ ISO Q9001-1994 Par. 4.6.4.2 Customer Verification of subcontracted product When specified in the contract the customer shall be afforded the right to verify conformance at the subcontractor's and supplier's facility. Par. 4.10 requires that all activities specified in the quality plan have been satisfactorily completed.

¹¹⁴ Buying Commercial and Nondevelopmental Items: A Handbook - Chapter 6, Product Assurance

The supplier shall provide for customer witnessing of Initial Production Lot Validation. These validation points and methods shall be documented in the quality planning documents. [JRM173]

5.5.3 In-process Inspections



TESTING

In-process inspections are required per ISO Q9002-1994 Par. 4.10.3. In-process inspection are usually considered to be an internal process for the commercial supplier and includes such activities a: job set-up and verification and process performance monitoring. In-process inspections are typically used where operations are not monitored by SPC and are called out in the control plan. Records of in-process inspections must be maintained by the supplier. In-process inspections do not usually include the customer and may not impede the production flow. The requirement below is added to allow the customer or their representative's to participate as a witness to the supplier's in-process inspections.

The supplier shall provide for customer witnessing of in-process inspections¹¹⁵ for product key characteristics that are not controlled by SPC. Appropriate sampling may be used and defined in the Program Control Plan.

CAUTION: Customer or representative in-process inspection is NOT a commercial practice and may preclude contracting with commercial suppliers or cause an increase in the product price. The production flow may not be impeded. The customer is usually allowed to "witness" the production process. If this task should be mutually agreed upon, the inspection or witness and frequency should be clearly defined in the contract or statement of objectives and in the supplier's program control plan.

5.5.4 Final Inspection

Final inspection and testing are required per ISO Q9002-1994 Par. 4.10.4. Final inspection is usually considered to be an internal process for the commercial supplier and includes such activities as visual, mechanical and test operations, ensuring traceability and product revision is correct, and performing inspections and tests per work instructions. Once the processes and instructions are in place for production runs, there is usually no need for final inspection and testing as many of the processes and in-line inspection and testing are automated. Results of the final inspection and test are recorded and maintained per customer requirements.

¹¹⁵ ISO Q9001-1994 Par. 4.10.3 In-process inspections

The supplier shall provide a report of final inspection results and a certification¹¹⁶ of final inspection for each unique serial number or lot as indicated in the contract and Program Control Plan.

5.5.5 Customer Witness of Final Acceptance

The customer is usually allowed to witness or “observe” the production process. The requirement below is added to include the customer or their representative’s participation as a witness to the supplier’s final inspection and/or acceptance testing. The production flow may not be impeded. Appropriate sampling may be used and defined in the Program Control Plan.

The supplier shall provide for customer witnessing of final product inspection¹¹⁷ and/or acceptance testing and a Certification¹¹⁸ of Final Acceptance for each unique serial number or lot as indicated in the contract and Program Control Plan.

CAUTION: Customer or representative witnessing of Final Acceptance Inspection is NOT a commercial practice and may preclude contracting with commercial suppliers or cause an increase in the product price. If this task should be mutually agreed upon, the inspection/witness and frequency should be clearly defined in the contract or statement of objectives and in the supplier’s program control plan.

5.6 Nonconforming Product Determination Authority

The objective for control of nonconforming product is to prevent further processing of defective products, to reduce future production rework or replacement costs and to ensure that the customer receives product that meets the performance requirements. To accomplish this it is necessary to establish controls for the identification, isolation, and disposition of discrepant product. The customer may wish to review and approve the supplier’s internal system for control of nonconforming product.



In the defense environment the process for controlling discrepant material is referred to as “Material Review” (MR). A defense customer grants Material Review Authority (MRA) to a supplier who has documented satisfactory controls and procedures are in place to isolate defective product, conduct material reviews and to dispose defective product that is produced or procured.

¹¹⁶ ISO Q9001-1994 Par. 4.10.4 Final Acceptance inspection

¹¹⁷ ISO Q9001-1994 Par. 4.10.4 Final Acceptance inspection

¹¹⁸ ISO Q9001-1994 Par. 4.10.4 Final Acceptance inspection

The supplier shall allow for final determination by the customer,¹¹⁹ or their representative, for “use as is” and “repair” dispositions and any major nonconformances.

5.6.1 Material Review Members

Quality assurance procedures should clearly address the qualifications of the functions involved in the determination process to ensure that dispositions are made by persons “competent to evaluate the effects”¹²⁰ on form, fit, function and interchangeability. It is suggested that the cross-functional team be included as material review members or advisors to disposition products. The team members represent various functions (design, purchasing, manufacturing and quality assurance) that should be advised of the defect and disposition in order to establish and implement timely and effective corrective actions¹²¹ for processes that created the defect. The next internal customer in the process should also be aware of, accept and agree to a nonconforming material disposition.

The supplier’s nonconforming material control procedures must identify responsibilities and authority¹²² for acceptance, rejection, and disposition of products. When material review authority from the customer is required, the company’s procedures may require tailoring as mutually agreed and documentation in the control plan or other appropriate document.

In either commercial industry or government the ultimate customer may require that the following dispositions be submitted for customer determination of acceptability.

- “use as is” or “repair” dispositions
- where the defect impacts product’s or system’s form, fit, functional or interface
- all government cost-type contracts, require customer or representative approval for any material review disposition.

5.7 Quality Records



Identification of records to be retained are frequently developed with the customer during the advanced quality planning. Quality records may be submitted to the customer to demonstrate system efficiency or improvement, or as justification for reduction of customer oversight.

ISO Q9001-1994 requires 16 quality records:

Note: ISO Paragraphs are shown in brackets [].

1. Management Reviews [4.1.3]
2. Quality Planning [4.2.3 h]

¹¹⁹ ISO Q9001-1994 Par. 4.13.2 “... reported for concession to the customer ...”

¹²⁰ ISO Q9004-1-1994 Par. 14.4 Nonconforming Product Review

¹²¹ ISO Q9001-1994 Par. 4.14 Corrective and Preventive Action

¹²² ISO Q9001-1994 Par. 4.13.2 Review and Disposition of Nonconforming Product

3. Contract Review [4.3.4]
4. Design Review [4.4.6]
5. Design Verification [4.4.7]
6. Sub-tier supplier valuations [4.6.2 c]
7. Control of Customer supplied product [4.7]
8. Traceability information [4.8]
9. Process Controls [4.9]
10. Receiving Inspection [4.10.2.3]
11. Inspection and Test records [4.10.5]
12. Control of Inspection and Test equipment [4.11, 4.11.2]
13. Review and Disposition Nonconforming product [4.13.2]
14. Corrective Action [4.14.2]
15. Internal audits [4.17]
16. Training records [4.18]

5.7.1 Record Retention

Individual contractors may elect to keep quality records for extended periods to assist in product trouble-shooting, warranty issues or as a self-protection against future litigation. The period for storage of records should be relative to the product operating life (20-45 years for some aircraft).

Supplier shall provide for Quality Records Retention and customer access, for the period of time¹²³ as stated in internal company procedures or as mutually agreed and defined in the contract or statement of objectives.

5.8 Continuous Improvement

A continuous improvement philosophy is a “best practice” necessary for a supplier to remain competitive, to reduce product cost and to improve delivery performance and the level of customer satisfaction.

- Key Characteristics
- Process Controls
- Measurement systems
- Inspection & Test Status
- Metrics
- Training



The supplier shall establish, document and maintain a Continuous Improvement Program¹²⁴ that is applicable throughout the organization and includes procedures, instructions and reporting of product or process variability reduction efforts together with monitoring of key characteristics.

¹²³ ISO Q9001-1994 Par. 4.16 “Retention times ... shall be established and recorded ... for a agreed period.

¹²⁴ ISO Q9004-1 Par. 5.6 Quality Improvement

The continuous improvement objectives and tools listed below are typical but not an exhaustive listings.

1. Establish clear goals
2. Training
3. Recognition of successes
4. Design of Experiments (DOE)
5. Computer Modeling or Simulation
6. Design for Manufacturability or Assembly (DFM/A)
7. Process-proofing (Mistake-proofing)
8. Inspection/audit points
9. Failure Mode and Effects Analysis (FMEA)
10. Performance risk assessments

Total Quality Management Techniques

- Parts per million analysis
- Pareto analysis
- Cause and effect diagrams
- Flow charts of critical processes

Statistical Process Controls and Control Charts¹²⁵

- Sampling techniques
- Control charts in use
- Management summary reports

Key Process Parameter Controls

- Process capability studies (Cp & Cpk)

Variance Reduction Program (VRP)

- Variance reduction is a continuous improvement “best practice” that relates specifically to design, manufacturing, assembly and test of the product. Requirements for variability reduction instructions are found in the Section 10 Manufacturing Processes & Controls VRP efforts are described in the Program Control Plan.
 - *NOTE:* A product variability reduction program is suggested as a possible area for supplier award/incentive fee that is mutually agreed upon.

5.8.1 Continuous Improvement Program Incentives

Variability reduction programs benefit both the customer and the supplier and as such may include contractual incentives. Continuous improvement goals, metrics for measurement of

¹²⁵ ISO Q9001-1994 Par. 4.20.2 Statistical Techniques - documented procedures

progress and frequency of review should be mutually established between the customer and cross-functional team members. The defense customer frequently includes an award fee for variability reduction efforts.

5.9 Cost-of-Quality

The cost-of-quality tracking is a “best practice” used by world-class suppliers. The actual costs of key processes are measured, tracked and compared with previous periods to determine the effectiveness of past corrective actions or continuous improvements.

Costs related to defect prevention, appraisal (for corrective action), failure (internal or external), correction (rework/repair) and scrap, have no equivalence in ISO Q9001-1994; but, ISO Q9004-1-1994, Guidelines for Quality Systems and Management, Par. 6.2.2, Financial Considerations of Quality Systems, discusses in detail the value of cost of quality reports to management.

Cost-of-quality data is used by the defense customer to determine the total life-cycle cost of a system including possible affects on maintainability and repairs, evaluation of a quality program effectiveness, and identification of cost drivers for non-conforming product. Cost-of-quality data and monthly reporting is suggested as a possible area for supplier award/incentive fee that is mutually agreed upon.

The supplier shall demonstrate their Cost-of-Quality¹²⁶ measurement system including internal management reporting and trend analysis.

CAUTION: Cost-of-quality reporting requirements are NOT a commercial practice and may preclude contracting with commercial suppliers. Suppliers are usually willing to demonstrate their internal practices during the initial supplier selection process. If this task for reporting of cost-of-quality information mutually agreed upon, the content and frequency should be clearly defined in the contract or statement of objectives and in the supplier program control plan.

Cost-of-quality data usually includes Prevention, appraisal and failure costs and may be shown as a percentage of sales or manufacturing added costs. Cost-of-quality should be collected, for specific contracts or products, on a continual basis and reported at least quarterly.

- Prevention:
 - Inspection & test planning
 - Qualification tests
 - sub-tier supplier development

¹²⁶ ISO Q9004-1-1994 Par. 6.2.2 a) Quality-costing approach

- Appraisal:
 - Inspections: Incoming, In-process, Final
 - Inspection & test equipment
- Failure:
 - Rework, repair or replacement, scrap (required by defense customers)
 - External: warranty, loss of business due to customer dissatisfaction
 - Other: production yield, first pass success, down time, loss of production

5.10 References

National standards available

- American National Standards Institute (ANSI):
 - ISO Q9001-1994, Quality Systems- Model, released August 1, 1994.
 - ISO Q9004-1-1994 Quality System Element - Guidelines
International Organization for Standardization (ISO)
 - ISO-10006 Guideline for Quality Assurance for Program Management (DRAFT)
 - ISO 10012-1:1992 Quality Assurance for Measuring Equipment

Commercial company's standards

- Boeing Aircraft Company
 - D1-9000 Advanced Quality Systems for Boeing Suppliers®
a registered trademark of Boeing Aircraft Company
- Automotive Industry Association Group: (AIAG)
 - QS-9000 Quality System Requirements
 - Advanced Product Quality Planning and Control Plan reference manual

DoD Handbooks

- Commercial and Nondevelopmental Handbook, April 1996,
- OSD-Standardization Program Division

6. Supplier Selection

Objective: To affect design, time-to-market, producibility, quality, profit and reputation.

This requirement for source selection policies and/or procedures addresses the selection of qualified suppliers and the periodic evaluation of their past performance. The technical and cost issues that are involved with down-selection are not addressed.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix¹²⁷. The supplier's own systems or processes must meet the intent of the ISO 9000 series and these requirements. The requirements for policies and/or procedures are shown below.

Requirement Title	Par.
1.6.1 Source Selection Policies, Procedures and Planning.....	6.1
2.6.4 Supplier Performance Rating System	6.4

These Source Selection requirements are based on the requirements established by:

- | | | |
|-------------------|------------|--|
| •ISO Q9001-1994 | par. 4.6.2 | Evaluation of subcontractors |
| •ISO Q9004-1-1994 | par. 9.3 | Selection of acceptable subcontractors |
| •ISO Q9004-1-1994 | par. 9.8 | Quality records related to purchasing |

Note: It is not required that the contractor's Source Selection process be based on the requirements of ISO 9000 Quality Requirements series. Other national standards or the supplier's own practices may also be used.

6.1 Source Selection Policies, Procedures and Planning

The source selection policies and procedures include:

- Internal Policies - level 1 documentation (See Section 5.3 Basic Quality System)
- Internal Procedures - level 2 documentation (See Section 5.3 Basic Quality System)

The supplier shall describe their internal process for management of Source Selection Policies and/or Procedures¹²⁸ which ensure that stated performance and reliability requirements will be satisfied.

¹²⁷ Organizational and Technical Interfaces BP Requirements Section 1

¹²⁸ ISO 9001-1994 par. 4.6 Purchasing

6.1.1 Source Selection Plan

When the supplier and sub-tier supplier existing source selection procedures do not adequately address customer requirements, a Source Selection Plan is developed and provided to the customer. This plan should clearly describe the organization and intended approach for compliance with the customer requirements.

This Source Selection Plan may be combined with the overall Program Control Plan and consists, at a minimum, of the following.

- Organization structure with defined roles and responsibilities
- Written summary (listing) of applicable policies and procedures, industry standards
- Evaluation criteria: technical, cost and performance factors
- Subcontractor controls¹²⁹ (business practice flow down requirements)
- Subcontractor performance reviews and audits¹³⁰.

Source Selection must be based on Technical, Cost and Performance factors including the following.

- The supplier's technical approach must be acceptable and in compliance with customer requirements and specifications, and national standards.
- Cost factors include competitive cost and cost containment initiatives such as design-to-cost and continuous process improvement.
- The performance risk factors address the supplier's product quality, on-time delivery, and responsiveness to customer needs and expectations.

The Source Selection Plan may be as simple as references to company procedures or may require a detailed outline with milestone events, depending on the product and program requirements. The type and extent of source selection planning is dependent on the type of product, complexity and criticality and is usually required only for major subcontracts. The controls placed on subcontractors is also dependent on the type of product they provide, the complexity and criticality, and where appropriate, the subcontractor's records of previously demonstrated capability and performance. Reference to existing plans in other functional areas is acceptable. The Source Selection Plan typically requires customer approval prior to implementation or for any changes affecting the intent of the plan. Figure 6-1. Supplier Selection Model, depicts a simplified supplier selection process for used by a commodity team. The process begins with a questionnaire together with supporting documentation, submitted by the supplier for review by the selection team. The team reviews the documentation for adequacy and determines the supplier capability to provide the product, based on complexity and prior qualifications. If necessary a supplier survey is completed. Corrective action, if needed, is taken by the supplier

¹²⁹ ISO 9001-1994 par. 4.6.2 b ... type and extent of control ... over subcontractors

¹³⁰ ISO 9004-1-1994 par. 9.8 Quality records related to purchasing ... availability of historical data to assess subcontractor performance and quality trends.

and approval is granted. Supplier performance reports are maintained and periodically reviewed for continuous improvements.

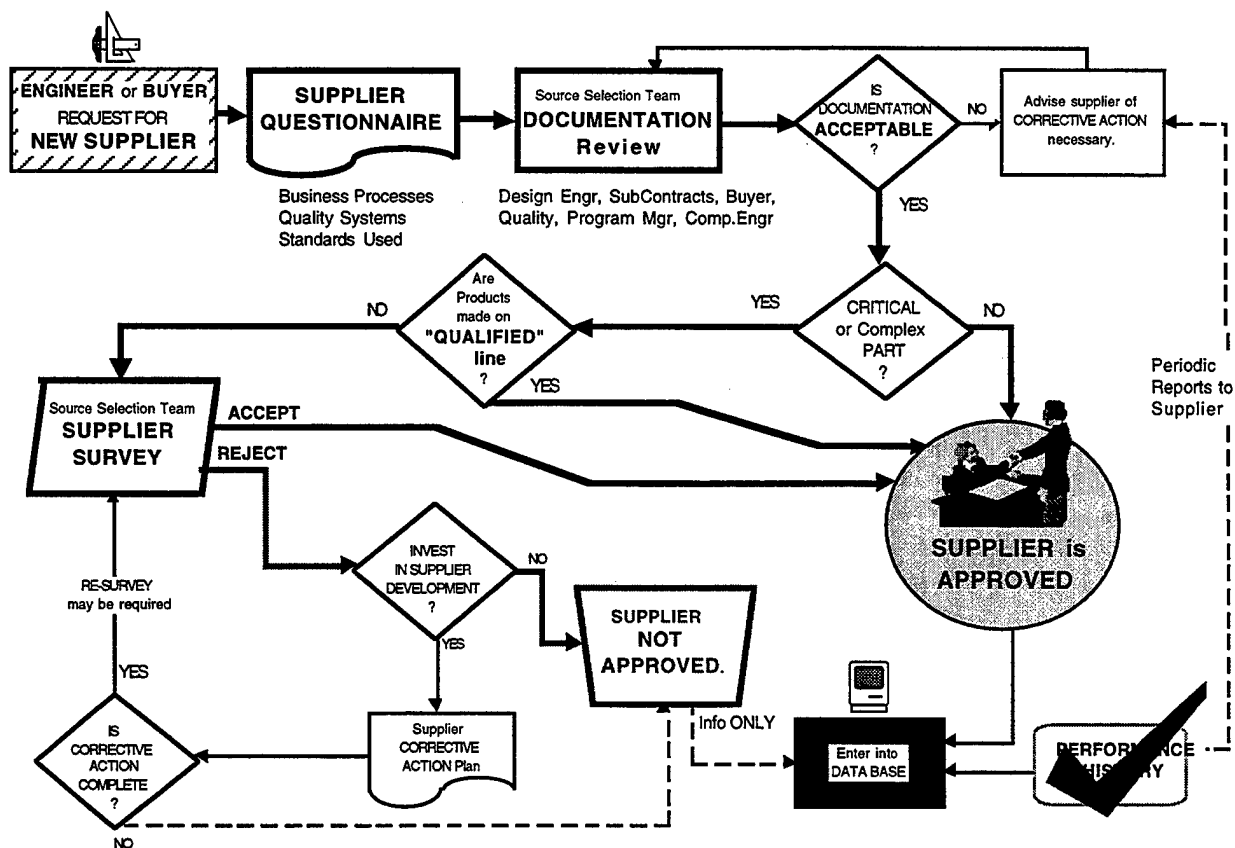


Figure 6-1. Supplier Selection Model

6.2 Source Selection Team

It is recommended that contractors establish a formal Source Selection team for high-dollar procurements, complex products or the establishment of long term, preferred supplier agreements. A source selection team or commodity team is composed of a cross-functional group¹³¹ who are technically capable within their areas, including engineers, finance, manufacturing, procurement and quality assurance personnel. The team should be convened prior to Preliminary Design Review (PDR) or initial Bill-of-material development to review/revise those items to be out-sourced and their classification.

Team responsibilities include the following.

- Establishing or tailoring of the supplier Self-Evaluation questionnaire for a specific commodity (par. 6.6 for Questionnaire information)

¹³¹ See Section 1.0 Organizational and Technical Interfaces

- Determining evaluation criteria/ weighting / relative importance of questions
- Assisting in the review of the product classification for sub-tier supplier quality requirements
- Participating in questionnaire evaluation and on-site evaluations
- Participating in past performance reviews.
- Participating in establishment of supplier Relationships (par. 6.8)
- Feedback to supplier regarding self-evaluation short falls with corrective action required prior to on-site survey and regarding performance reviews.

6.3 Facility Survey Requirements

A facility survey is required when the product complexity or critical applications warrants an audit of supplier processes. The Source Selection Plan should describe the circumstances that will require facility surveys to be performed.

The initial audit should consist of the Basic Quality System and Statistical Process Controls (SPC) reviews. Depending on the program phase, individual advance quality concepts (AQC) may also be reviewed during the initial audit. Advanced quality concepts that are appropriate and critical to the delivery of conforming products may be audited during subsequent performance evaluations. The level of detail will vary for new suppliers, who have procedures and infrastructure but have not provided products. For existing suppliers, the emphasis should be placed on adequate product historical data with less emphasis on infrastructure documentation. (see section 5.3 Quality Systems Model).

6.4 Supplier Performance Rating System

The supplier shall describe and demonstrate how past performance information and periodic evaluations are used in future source selection decisions and the management of the existing supplier base.

6.4.1 Performance Risk Factor

Supplier rating systems generally include an objective measurement of past performance and subjective evaluations of a supplier's compliance with standards and commitment to customer satisfaction. These ratings are used, in varying ways, in the future source selection decision to estimate the potential performance risks. The objective numeric rating may be used to "factor" a supplier's bid, illustrating the "total cost of ownership vs. the total value received." The subjective rating of the supplier's cooperation and responsiveness is also taken into consideration by the source selection committee. These ratings may also be used to determine the level of detail required in audits or the amount of supplier surveillance that is warranted based on past performance. (*Note:* The more metrics that are agreed upon, the less customer oversight should be required.)

A past performance reporting system may include the following.

- Objective elements such as:
 - Product quality, including data from inspections performed at incoming/receiving inspection, at the supplier, and rejections from the assembly line that are attributable to the supplier,
 - On-time delivery performance, based on receipt date for acceptable product as compared to the contractual promise date.
- Subjective elements such as:
 - Management cooperation or responsiveness
 - Willingness to share information
 - Cost improvement or control goals (design-to-cost)
 - Continuous Process Improvement goals.

Suppliers with no “past performance experience” should not be penalized unless it can be demonstrated that the lack of “product (technical) experience” would represent a higher risk to the customer.

These supplier ratings should be centrally maintained and be periodically updated in a database or reporting system. Production suppliers are reported separately from non-production suppliers but may use the same rating system.

6.4.2 Periodic Evaluation

The supplier shall describe the requirement and frequency for subcontractor evaluations (par. 6.7 for registration information.)

The an on-site audit may not be necessary when the supplier rating system is functioning properly, on-time delivery and product quality is acceptable, and the supplier’s continuous process improvement goals are being met.

Note: Supplier evaluations by industry take many forms from reviewing past performance to re-auditing at established periods.

The supplier should be evaluated to ascertain problems that may be causing poor performance. The following circumstances should require an audit.

- Poor quality and delivery performance rating within past 12 months
- Supplier not meeting agreed improvement goals¹³².
- No product receipts within last 2 years
- Critical management changes have occurred
- Facility relocated and process controls changed

¹³² QS-9000 Attachment A, pg. 76

An information feedback system should be established for all supplier evaluations. Past performance results should be reviewed with subcontractors in the spirit of continuous improvement.

6.5 References

The following non-government standards were reviewed during the development of these requirements:

- American National Standards Institute/ American Society for Quality Control
 - ISO 9001-1994 Quality Systems-Model for Quality Assurance in Design, Development, Production, installation, and servicing.
 - ISO 9004-1-1994 Quality management and quality system elements - Guidelines.
- QS-9000, Quality System Requirements, August 1994 Chrysler Corporation, Ford Motor Company, General Motors Corporation Quality System Assessment, Chrysler, Ford, GM, August 1994.
- Supplier Requirements Manual, TRW Automotive Electronics Group, April 1994.
- Audit Preparation and Survey Guidelines, TRW Automotive Electronics Group, 04/95.
- D1-9000® Advanced Quality Systems® for Boeing Suppliers, 1995.
- Supplier Certification, Clemson University College of Commerce and Industry, 1991.

The following first tier Military requirements documents were reviewed during the development of these requirements.

- MIL-Q-9858A, Quality Program Requirements;
2/27/95: Canceled per OSD DSIC effective 10/96.
- MIL-STD-1535A, Supplier Quality Assurance Program Requirements, February 1974.
Canceled per OSD DSIC 5/31/95.
- Air Force Pamphlet 63-502, Guide to Air Force Acquisition Quality Program, Draft dated July 20, 1995.
- Performance Risk Assessment Group Desk Guide, Joint Aeronautical commander's Group, Draft August 31, 1995

Note: This attachment is NOT a requirement, but is provided as a possible "best practice".

6.6 Subcontractor Self-Evaluation

In preparation for the supplier selection process, a self-evaluation questionnaire should be developed for specific commodities by the product team. It is suggested that this self-evaluation questionnaire requires the supplier to input a written response, not a simple "yes/no" checkoff. The form should be available in electronic format to facilitate on-line completion by the supplier and to establish an electronic record for future reference at the customer. All new suppliers

should be required to complete this self-evaluation and submit it to the customer for their review. This questionnaire will provide a preliminary look at the supplier's capability and controls. Not all suppliers will require a facility survey, depending on the product complexity and ownership of the design. A facility survey should add value to the selection process. An extensive questionnaire should provide sufficient information to justify placement of non-critical or non-complex products with the candidate supplier.

6.6.1 Business practices

The self-evaluation should include:

- a written description of Policies & Practices
- copies of manual Cover page, index and revision record pages only; complete documents are not required, but specific documents of interest may be requested at a later time or reviewed during a facility survey.
- a management vision and mission statements, organization charts and qualification or background information.
 - quality products and customer satisfaction must be a driving forces within your company. Provide evidence of customer satisfaction, awards and dates.

6.6.2 Basic Quality Systems

- Describe Standards used for your basic quality systems (ISO 9000)
- Describe your Strategic Quality Planning objectives
- Describe your Continuous Process Improvement initiatives

6.6.3 Advanced Quality Concepts

Describe and demonstrate with examples, the analytical techniques used to eliminate variances or non-conformities (typical examples):

- Statistical Process Control (SPC)
- Control charts
- Quality Function Deployment (QFD)
- Design of Experiments (DOE)
- Design for Manufacturing (DFM)
- Design Verification (DV)
- Critical Path Method (Pert/Gantt)
- Benchmarking
- Cause & effect diagram (fishbone)
- Production part approval
- Manufacturing process controls
- Mistake proofing
- Test capability

Attachment A - System Audits

Note: This attachment is NOT a requirement, but is provided as “information only”.

6.7 Systems Audits

Systems audits/surveys ensure that the supplier is conducting business in compliance with their established procedures or control plans and that those procedures, processes and results will meet the customer’s requirements. These audits do not relieve suppliers from ensuring quality of subcontracted parts, materials or services.¹³³ Each customer must determine which approach is acceptable to meet their goals and objectives. These System Audits include:

- A First-party audit which consists of an internal self-audit conducted by a functionally “independent” auditor to ensure that the procedures are clearly understood and performed by the employees.
- A Second-party evaluation is usually conducted by a customer or industry association. Assessments by other customers in a similar industry may be acceptable when evidence of surveys is provided to the customer requesting evaluation.
- A Third-party assessment is referred to as a Formal registration and is conducted by an accredited certification body such as:
 - ISO
 - National Standards Authority of Ireland
 - Underwriters Laboratory
 - Other certified accreditation bodies

Note: There is no DoD or Air Force policy requiring Registration.

¹³³ QS-9000 par. 4.6.2 Note

6.8 Supplier Relationship Levels

Note: This attachment is NOT a requirement, but is provided as a possible “best practice”.

Lean Aircraft Initiative (LAI) 8/95: LAI is a consortium of defense contractors and academia which is led by Massachusetts Institute of Technology (MIT). Their purpose is to identify the best practices in industry that may be adopted in defense contracting. The excerpt shown below is taken from the LAI Supplier Focus Group. Figure 2. Suggested Supplier Relations Hierarchy depicts this objective.

- Overarching practices in supplier selection: “Ingrained design processes which pro-actively involves preferred suppliers in part, process and performance decisions from pre-proposal through product realization” and “Substantial and increasing percentage of dollar volume transacted through supplier partnerships and long term agreements...”

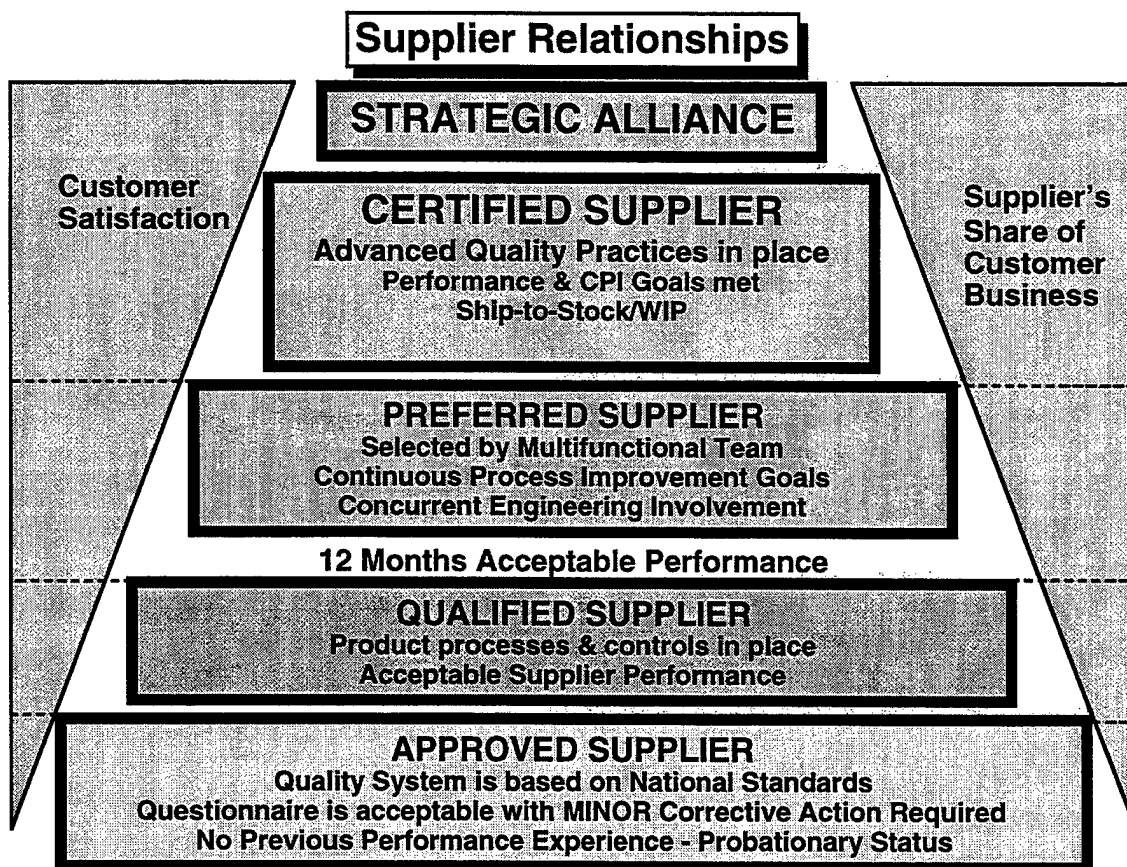


Figure 2. Suggested Supplier Relations Hierarchy

6.8.1 Strategic Alliance supplier

A strategic alliance is a formal agreement between companies, established at the corporate management level, which offers a strategic advantage (a.k.a. joint venture or cooperative agreements).

- Benefits:
 - Core competencies of each company are used to obtain the lowest cost, reduction of risk, and highest technological products to meet a customers requirements with an improved time-to-market.
- Responsibilities:
 - Sharing of design and development or supply capabilities
 - Sharing of proprietary technical information
 - Compatible technological products or processes

6.8.2 Certified Supplier

- Benefits:
 - same as Preferred supplier PLUS
 - periodic re-audits are not required
 - (excluding new program plans that may be required)
 - ship-to-WIP (Work-In-Process or Stock)
A Designated Supplier Quality Representative may be established, by the customer, from the supplier's Quality personnel to accept product for the customer at the supplier's plant.
- Responsibilities:
 - Continuous Process Improvement (CPI) goals met.

6.8.3 Preferred Supplier status

- Benefits:
 - same as QUALIFIED supplier PLUS
 - Concurrent engineering involvement
 - Selected by cross-functional team
 - Long term agreement or commitment established
- Responsibilities:
 - Advanced quality planning for defect prevention or variation reduction, FMEA, etc.

6.8.4 Qualified Supplier status

- Benefits:
 - Lot sampling used at incoming quality control
- Responsibilities:
 - Acceptable performance history: Quality & Delivery

6.8.5 Approved Supplier status

- 1) Benefits:
 - Allowed to submit bids for new requirements
 - New suppliers begin with a PERFECT supplier rating.
- 2) Responsibilities:
 - 100% inspection by incoming quality control
 - probationary status; establish a proven quality history (below)

6.8.6 Proven Quality History

Typical examples for establishing a “proven quality history” include:

- TRW Automotive Electronics:
 - 12 months as Approved supplier
- TRW Avionics Systems Division:
 - 12 months with acceptable Supplier Performance Rating
- Lockheed Martin Tactical Aircraft Systems:
 - 6 months as Approved supplier
- Boeing Defense & Space Systems:
 - each situation is determined on it's merits.
- McDonnell Douglas:
 - 99% Quality & 99% On Time history for 12 months
- AT&T:
 - 10 consecutive acceptable lots and 6 months to proceed to next levels

7. Procurement Controls

Objective: To provide material, supplies and services in an efficient and timely manner to our internal users and to provide clear communication of requirements, delivery and acceptance criteria to suppliers, while obtaining the best competitive price.

This requirements document was developed with the cooperation of commercial industry and defense contractors best competitive practices and is based on ISO Q9001, Par. 4.6 and 4.6.3, and ISO Q9004-1-1994. These requirements do not intend to specify a national standard, but allow the supplier to select any national standard or develop his own methods, as long as they "meet the intent" of all customer and Business Practices Requirements. The requirements developed in this document are only "applicable" when specified in the Contract, Statement of Work or Operational Requirements Matrix¹³⁴. The supplier's own systems or processes must meet the intent of ISO 9002 and these requirements. The requirements for policies and/or procedures are shown below.

Requirement Title	Par.
1.7.1 Procurement Procedures	7.1
2.7.4 Procurement System Evaluations	7.4

7.1 Procurement Procedures

The supplier shall establish and maintain Procurement Procedures¹³⁵ to ensure internal review and approval of procurement documents, and the proper communication of contractual requirements, product requirements, and technical data to sub-tier suppliers.

7.2 Procurement Data

Procurement data is defined as information contained in the contract, subcontract, statement of work, purchase order or other suitable acquisition documents that clearly describes to sub-tier suppliers the product being ordered including quantity, price, specifications, technical data, contractual clauses, terms and conditions, quality system requirements, and acceptance criteria.

The following procurement data is considered to be the minimum necessary for proper requirements communication.

- Product description¹³⁶
 - Part number, Description or statement of work
- Unit price

¹³⁴ See Section 1.0 Organizational and Technical Interfaces

¹³⁵ Ref. ISO 9001-1994 Par. 4.0, 4.1.1, 4.2.2, 4.2.3, 4.6.2, 4.6.3

¹³⁶ Ref. ISO 9001-1994 Par. 4.6.3

- Quantity required
- Quality system or product quality level requirements¹³⁷
- Required delivery date
- Payment terms, FOB point (free on board) and prompt pay discounts
- Acceptance criteria
 - Certificate of conformance¹³⁸ or warranty
 - Receiving or source inspection¹³⁹
 - Acceptance test data
 - Qualification tests

Note: Where verification of purchased product at the subcontractor's facility is required, the supplier shall clearly specify the requirements for acceptance.

7.3 DPAS Priority Rating

Defense-related prime contracts require the inclusion of the Defense Priority and Allocation System (DPAS¹⁴⁰) clause for national defense programs and includes any product, service, or material which requires preferential treatment or priority basis over all other contracts and to allocate materials and facilities in such a manner as to promote the national defense. However, the DPAS priority rating should not be applicable to "commercial items."

CAUTION: Use of the Defense Priority clause is NOT a commercial practice and may preclude contracting with commercial suppliers. If this task is mutually agreed upon, the Purchase Order Clause, requirements for Government's rights to affect a supplier or sub-tier supplier's production scheduling and "acknowledgments" should be clearly defined in the contract or statement of objectives and in the supplier's program control plan.

7.4 Procurement System Evaluations

The supplier shall provide evidence of periodic, independent, internal Procurement System reviews¹⁴¹ to ensure compliance with company policies and procedures.

The procurement system evaluations, significant findings, corrective action taken, feedback provided to individuals involved and other purchasing metrics should be summarized for presentation to management and may be required for submission to the customer.

¹³⁷ Ref. ISO 9001-1994 Par. 4.6.3

¹³⁸ FAR 46.504 Certificate of Conformance ... may be used in certain instances instead of source inspection ... government's interest, small losses in event of defect, contractor's reputation and past performance.

¹³⁹ Ref. ISO 9001-1994 Par. 4.6.4

¹⁴⁰ FAR 52.211-15 Defense Priority and Allocation Requirements (15 CFR Part 700)

¹⁴¹ ISO 9001-1994 Par. 4.1.3 Management review

CAUTION: Periodic external procurement system review is NOT a commercial practice and may preclude contracting with commercial suppliers. If this task is mutually agreed upon, the procurement system review should be accomplished during the Supplier Selection process. If subsequent reviews are necessary, they should be clearly defined in the contract or statement of objectives and in the supplier's program control plan.

Attachment A - 7.5 Procurement Metrics Report (par. 7.5) is shown to provide some ideas for procurement metrics.

Attachment A - Procurement Metrics

This Attachment is NOT a requirement, but is intended to provide possible metrics for continuous improvement of the procurement system.

7.5 Procurement Metrics Report

Procurement metrics should be established by the supplier and reported to upper management on a periodic basis. The intent is to provide meaningful metrics for the supplier to ascertain that proper controls of the procurement process are in place and continuous improvement and corrective action activities are effective.

These metrics (examples below) may be provided to the customer as demonstration of procurement controls to warrant reduced customer oversight. World class companies use benchmarks to establish a baseline for improvement metrics.

Note: It is suggested that a report be generated at a minimum on a semi-annual basis from information contained in the supplier's existing procurement system and contain 2-3 pages of summary level information to indicate procurement trends as compared to benchmarks established or to internal company goals and objectives.

Procurement Metrics for your consideration

↑ ↓ indicates an Increase or Decrease in trend for metric. Circle one.

Acquisition Cycle Time Reduction:

Objective: Reduction of acquisition cycle time.

- Definition: Cycle Time Reduction is the elapsed time from when a requirement is identified until the product is received in useable condition and includes: Drawing release, Purchase Requisition, Quotes, Supplier selection, Date PO placed, Receipt of product.
- Efficiency of the Acquisition (cycle) time: Goal: _____ Cal.days ↑ ↓

Optimization of Supplier Base:

Objective: Establish "teaming" or "preferred" relationships with a few select suppliers and reducing the marginal or mediocre suppliers. Increasing the supplier's share of business by early involvement will provide reduced costs or improve products.

(Separate production, overhead and MRO suppliers.)

- Number of production suppliers: Goal: _____ ↑ ↓
- Number of Strategic or Certified suppliers: Goal: _____ ↑ ↓
- Average Procurement \$ per production supplier: Goal: _____ \$ _____ ↑ ↓

Procurement or Supplier-generated savings:

Objective: Reduced costs for supplier; reduced prices for customers.

- % of dollars awarded by competition Goal: _____ % or [] Not tracked
- Buyer-negotiated savings, New suppliers (competition), or Design changes recommended by your suppliers Goal: _____ \$ _____ Saved
- Cost reduction based on Cost Improvement goals established with customer. Percent cost reduction for procurements Goal: \$ _____ \$ _____ % Saved

Supplier Lead-time:

Objective: Improve cycle times for faster time-to-market.

- Deliveries that met the requested on-dock or JIT required date.
(Was the product delivered when required?) Goal: _____ % _____ %
- Is supplier delivery performance tracked in your rating system? _____
Average On-Time delivery: Goal: _____ % _____ % of lots On-Time ↑ ↓

Defective Products:

Objective: Establish continuously improving goals for supplier's product acceptance at receiving inspection, source inspection, or production line or field failures.

- Quality level for all suppliers Goal: _____ PPM or % ↑ ↓
- Discrepancy Reports issued: Goal: _____ % ↑ ↓
- Returns to suppliers: (Lots) Goal: _____ % ↑ ↓

Socio-economic Procurement Summary:

- Small, Disadvantage Business Goal: _____ % or [] Not tracked
- Minority Business Goal: _____ % or [] Not tracked
- Woman-owned Business Goal: _____ % or [] Not tracked

Results of Procurement System audits

Objective: Demonstrate that proper controls are in place and being reviewed by management for reduction or elimination of customer surveillance. Audits conducted since the last periodic report.

Internal Corporate Audits

- Audit conducted by: _____ Date of Audit: _____
- Corrective Action required: _____ Date of Audit: _____

External Customer Audit/Verification

- Audit conducted by: _____ Date of Audit: _____
- Corrective Action required: _____

8. Customer Property Controls

Objective: To ensure customers that their property is being properly utilized and protected.

These business practice requirements do not intend to specify a national standard, but do intend to allow the supplier to select any national standard or develop his own standard methods as long as they meet the intent of all customer and the Business Practices Manual requirements.

- Definition: Customer Property comprises any plant equipment, or personal or real property, or material where title is vested in the customer and is subsequently furnished to a supplier for performance of a contract.
- Definition: Sensitive Property is property that is potentially dangerous to the public safety or security if stolen or lost, or is subject to exceptional physical security, protection, control or accountability, including national security classified items, controlled substances, hazardous materials, or precious metals.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix¹⁴². The supplier's own systems or processes must meet the intent of ISO 9002 and these requirements. The requirements for policies and/or procedures are shown below.

Requirement Title	Par.
8.1 Customer Property Policies, Procedures and Control Plan	8.1
8.3 Customer Property Identification, Care and Reporting	8.3
8.4 Disposal of Customer Property	8.4

Note: Government-Furnished Property (GFP) or Customer-Furnished Property (CFP) is referred to in this manual as *Customer Property* when the property is supplied by a customer who is either the Government or an Original Equipment Manufacturer (OEM) or any higher tier in the supply chain.

These customer property management practices are based on ISO Q9001-1994 Par. 4.7, the National Property Management Association, the Aerospace Industry Association (AIA) recommendations, and industry competitive practices. These property management requirements direct that suppliers establish and maintain procedures and practices to protect and manage customer property.

These requirements assume that a commercial supplier will be performing against a firm, fixed-price contract to provide products to the Government.

¹⁴² Organizational and Technical Interfaces BP Requirements Section 1

Note: When the product is provided under a Government, cost-type contract, the customer-supplied property definition includes products acquired by the supplier for use in development, manufacture, test or maintenance.

The following customer concerns are the basis for these business practice requirements:

- Customer property management system procedures
- Usage limited to contract intent (Commingling of inventory)
- Maintenance of customer property
- Reporting loss or destruction (Records and Reporting)
- Return of property (Contract close-out)

Other contract types, facilities and the supplier's acquisition of Government-owned property may require additional oversight and reporting requirements under the current regulations and are not discussed here.

8.1 Customer Property Policies, Procedures and Control Plan

A policy statement regarding use of customer property only as authorized must be included in the policies or procedures.

The supplier shall describe their internal process for management of customer-owned property¹⁴³ which ensures that stated performance and reliability requirements will be satisfied.

8.2 Customer Property Management Model

Figure 8-1. Property Control Model is a simple overview of the 3 elements necessary for an adequate property control system property control procedures and processes, proper care and use of property while in possession, and finally disposal of customer property according to their instructions. The supplier may use a manual tracing system or may use computerized tracking with an end result able to retrieve or report the status of the customers property at any time.

¹⁴³ ISO 9001-1994 par. 4.7 Control of Customer-Supplied Product (procedures)

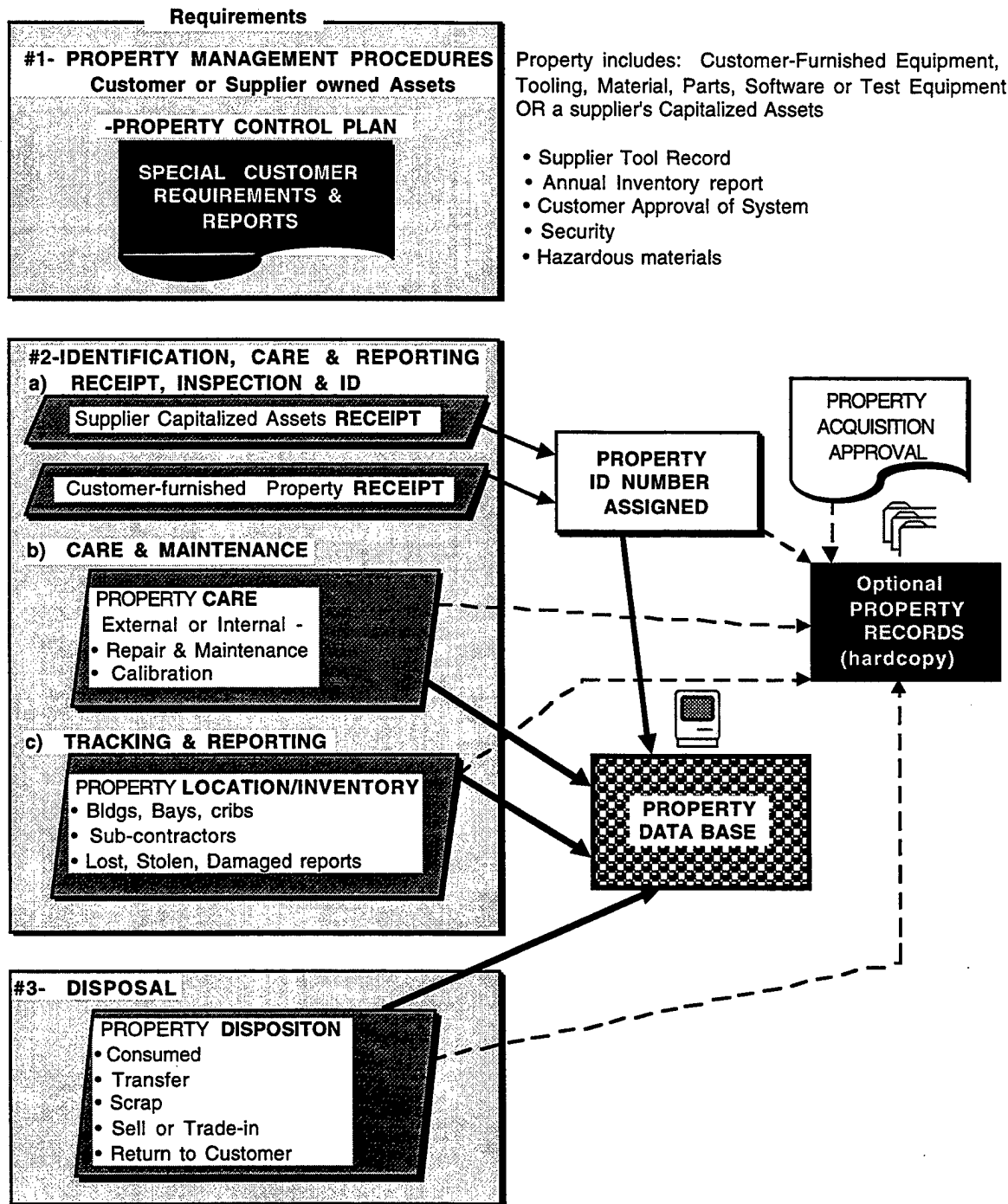


Figure 8-1. Property Control Model

8.2.1 Property Control Plan

When the supplier's existing property control systems and procedures do not adequately address a customer's requirements, a Property Control Plan is developed to clearly describe the organization and intended approach for compliance of the supplier's and sub-tier supplier's property controls and may be combined with the overall Program Control Plan. A Property Control Plan typically requires customer approval prior to implementation or for any changes affecting the intent of the plan. A typical plan contains the supplier's proposed methods for addressing, at a minimum, the:

- Supplier's internal controls including (a) policies, Procedures, national or industry standards used, (b) organizational structure with defined roles and responsibilities including points-of-contact, and (c) maintenance plan when special maintenance requirements for customer property exceed the supplier's normal maintenance process and,
- Project-unique handling and storage of customer property such as (a) classified products, hazardous materials, or prevention of commingling of customer and supplier property, (b) reporting requirements or annual property reports, and (c) supplier's property records constitute the official property records unless an exemption is authorized and released from liability.

8.3 Customer Property Identification, Care and Reporting

Customer-owned property should be cared for in the same manner as the supplier-owned property. Customer-owned property is identified on receipt, labeled per customer instructions, and is not physically commingled with other contract material nor with the supplier's material. Reporting requirements are determined by mutual agreement and are documented in a Property Control Plan.

The supplier shall:

- a) **verify¹⁴⁴ the identify and condition of customer property upon receipt**
- b) **provide proper care, maintenance, and storage of customer property**
- c) **ensure that customer property is not physically commingled with other product, either customer-owned or from other sources, and that the customer property is not used in other contracts¹⁴⁵**
- d) **maintain a recording and reporting system to track customer property to include receipt at the supplier, inventory transactions (issues and receipts), scrap, loss, damage, location and returns**
- e) **track and report customer property in the possession of subcontractor**

¹⁴⁴ ISO 9001-1994 par. 4.7 Control of Customer-Supplied Product (verification)

¹⁴⁵ ISO 9001-1994 par. 4.15.3 Handling, Storage, Packaging, Preservation & Delivery,
ISO 9001-1994 par. 4.7 Control of Customer Supplier Product

8.4 Disposal of Customer Property

The supplier shall dispose¹⁴⁶ of customer-owned property according to customer written instructions at conclusion of the contract or when no longer needed, whichever is sooner.

The requirement for coordination and communication with a government property clearing officer is determined by mutual agreement and is documented in a Property Control Plan. Use of government-specified forms is usually necessary.

8.5 References

National standards available

- American National Standards Institute (ANSI):
ANSI/ASQC Q9001-1994, Quality Systems- Model, August 1, 1994.
- Automotive Industry Association Group (AIAG):
QS-9000 Quality System Requirements
- National Property Management Association (NPMA): Property Manual DRAFT
- Aerospace Industries Association of America:
Government Property Control recommendations 8/96 DRAFT

8.6 Reference Information Only: Requirements Matrix

The business practice requirements were developed, by referencing the 16 requirements stated in FAR 52.245-3 and the Aerospace Industries Association recommended FAR re-write requirements contained in the Draft dated 8/96. Table 8-1 shows the correlation between the three requirements sources (ISO, FAR, & AIA).

Requirements based in ISO Q9001-1994 are shown in **BOLD**.

¹⁴⁶ FAR 52.245-2 Reqmt (i) Final Accounting and disposition...
FAR 45.6 Reporting, Redistribution, and Disposal of Contractory Inventory

REQUIREMENTS	ISO Q9001-1994 Other Nat'l Stds (AIA Draft 8/12/96)	CUSTOMER PROPERTY CONTROL 16 REQUIREMENTS per FAR 52.245-3 re-write 8/96
Policy Statement	AIA Draft #5	1) use only as authorized • FAR 45.102 (c); 45.509-2
PROCEDURE	Q9001: 4.7 procedures AIA Draft #16	2) Document procedures • FAR 45.502 (a); 52.245-2 (e)(2)
IDENTIFICATION	AIA Draft #3,#11	3) identify and entered into Property System - FAR 45.506; 52.245-3
RECEIPT & INSPECTION	Q9001: 4.7 verification AIA Draft #2	4) inspected upon receipt • FAR 45.502-1
CARE	Q9001: 4.7 maintenance AIA Draft #6	5) maintenance is scheduled, performed and recorded FAR 45.509-1
CARE	Q9001: 4.7 storage AIA Draft #12	6) handling & storage is appropriate for property FAR 45.509
Customer Reqmt: Loss Report	Q9001: 4.7 lost, or damaged AIA Draft #8	7) Reporting Lost, stolen, damaged property
Inventory & Storage records	Ref. Q9001: 4.15.3 AIA Draft #4	8) inventory distributions and returns are controlled
Recording & Reporting	Q9001:4.7 recorded AIA Draft #3	9) records are accurate and timely • FAR 45.505a; 45.505-1; 45.505- 14
Recording & Reporting (INVENTORY)	AIA Draft #7	10) periodic physical inventory • Inventories: FAR 45.508 (based on established practices) • Multi-contract cost and material control: At least annually per FAR 45.505-3 f. 1. vi
REPORTING	Q9001: 4.7 lost, damaged or is otherwise unsuitable	11) scrap is recorded FAR 45.505-8
Tracking & Reporting	Q9001: 4.7 lost, damaged or is otherwise unsuitable	• material consumed or scrapped is recorded FAR 45.505-8
Tracking Spcl Customer Reqmt	Ref. Q9001: 4.6.2b ... define type and extent of control ... over subcontractors. AIA Draft #13	12) subcontractors comply with requirements 45.502, 45.504c, 45.505a, 45.510 52.245-6 (k)
DISPOSITION	AIA Draft #14, 15	13) report when property is no longer needed FAR 45.102 (f); 45.502(g); 45.6

Table 8-1. Basis for Customer Property Control Requirements

Spcl Customer Reqmt Supplier Selection. Ref.: Supplier Select.	Ref. Q9001: 4.6.2a Evaluation of ... ability to meet subcontract AIA Draft intro.	1) customer approved property system • <i>NOT REQ'D in FAR Re-write</i> • FAR 45.104, 45.502(a); 45.511
Spcl Customer Reqmt SECURITY or HAZMAT	AIA Draft #12 (store & secure)	2) special security for classified or sensitive (or hazardous) property CLASSIFIED PROPERTY SEE PLANT SECURITY FAR 52.204-2 requirement in contract.

Table 8-1. Basis for Customer Property Control Requirements (Continued)

9. Handling, Storage, Packaging & Delivery Control

Objective: To avoid product damage in manufacture, storage and shipping.

Handling, storage, packaging and delivery of the products requires protection of its form, fit, and function during manufacturing or assembly and during shipment and storage at the customer site. These requirements are adequately addressed by the ISO 9001 standards. Commercial practices tend to satisfy most shipments, but unique customer requirements may require additional instructions for marking of packages, or unusual environmental conditions. These instructions are usually found in the statement of objectives or the contract. This is an area where a clear understanding by both parties is important. The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix¹⁴⁷. The supplier's own systems or processes must meet the intent of ISO 9002 and these requirements.

Requirement Title	Par.
• •9.1 Handling and Packaging Policies, Procedures	9.1
• •Packaging	9.2
• •9.3 Bar Coding	9.3
• •9.4 Handling, Preservation and Protection	9.4

9.1 Handling and Packaging Policies, Procedures and Planning

The supplier shall describe its internal Handling and packaging procedures¹⁴⁸, processes, standards, and tests to ensure that products are handled, stored, preserved, packaged, labeled, documented and shipped in a sufficient manner to prevent damage, deterioration, degradation, loss, or substitution of the product and to otherwise protect the Form, Fit or Function of the product.

9.1.1 Handling and Packaging Plan

When the supplier existing handling and packaging systems and procedures do not adequately address a customer's requirements, a Handling and Packaging Plan is developed to clearly describe the organization and intended approach for compliance of the supplier's and sub-tier supplier's handling and packaging controls and may be combined with the overall Program Control Plan. A Handling and Packaging Plan typically requires customer approval prior to implementation or for any changes affecting the intent of the plan. The Handling and Packaging Plan consists, at a minimum, of a description of the supplier's internal controls including: (a) Policies and Procedures, National or Industry Standards used, (b) organizational structure with defined roles and responsibilities, and ability to meet the project-unique packaging requirements.

¹⁴⁷ Organizational and Technical Interfaces BP Requirements Section 1

¹⁴⁸ ISO 9001-1994 Par. 4.15 Handling, Storage, Packaging, Preservation, and Delivery

9.2 Packaging

The supplier shall package the product for protection after final inspection and test, during delivery of the product to the customer,¹⁴⁹ and during storage at the customer's facility in conformance to federal and state requirements and to the customer requirements as stated in the contract.

Note: Additional defense customer handling, storage, packaging, preservation and delivery instructions may be found in the performance specification or statement of work.

Most discrepancies found in receiving inspection are from the lack of proper documentation, test data or other packing information. These simple "paper work problems" also affect the supplier's performance rating. The cost of ownership is increased for each rejection.

- Ref. ISO 9001 Par. 4.7 The supplier shall establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supplied product. ISO 9001 Par. 4.15.3 The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. ISO 9001 Par. 4.15.4 The supplier shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

9.3 Bar Coding

Bar coding of the external packaging is required. Bar code symbology shall be as specified in the statement of objectives or product performance specifications¹⁵⁰.

9.4 Handling, Preservation and Protection (ESD)

As applicable, sensitive electronic devices shall be protected from electro-static, electro-magnetic, magnetic and radioactive forces by properly safeguarded work stations and properly outfitted personnel during fabrication, assembly, test processing or packaging, and by the use of electrostatic discharge protective packaging materials during storage and shipment.¹⁵¹

- Ref. ISO 9001 Par. 4.15.5 The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

¹⁴⁹ ISO 9001-1994 Par. 4.15.4 "...conformance to specified requirements."

¹⁵⁰ ISO 9001-1994 Par. 4.15.4 Packaging
MIL-STD-2073 DoD Standard Practice for Military Packaging Par. 4.1.1;
MIL-STD-130 Identification Marking of US Military Property (Standard Practice)

¹⁵¹ ISO 9001-1994 Par. 4.15.5 Preservation

9.5 References

The following Non-Government Standards were reviewed during the development of these requirements:

- ISO 9001-1994 Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing

10. Production Process Control

Objective: To optimize process yield

The business practice objective is to establish manufacturing processes and controls requirements that are acceptable by commercial suppliers for defense acquisition. Performance-based requirements are contained in the product specification. Many of the design, quality and reliability “control points” are discussed in other sections of this manual.

- Definition: Manufacturing process control is the functional discipline of measuring, observing, reporting and managing the output of manufacturing or assembly operations.
- AIAG Advanced Product Quality Planning:
Operations may be controlled by, but are not limited to, Statistical Process Control, inspection, attribute data, mistake-proofing, and sampling plans.

The requirements developed in this document are only applicable when specified in the contract, statement of Work or Operational Requirements Matrix¹⁵². The supplier’s own systems or processes must meet the intent of ISO 9002 and these requirements.

Requirement Title	Par.
1. 10.1.1 Manufacturing Planning.....	10.1.1
2. 10.1.2 Approval of Manufacturing or Assembly Processes	10.1.2
3. 10.1.5 Process Capability Study	10.1.5
4. 10.2.1 Reporting Process Controls and Improvements.....	10.2.1
5. 10.3 Demonstrations of Operational Controls	10.3
6. 10.4.1 Variability Reduction Instructions	10.4.1

The intent of this document is to inform the potential supplier of some of the more value-added process controls being used in commercial industry and in defense-related acquisitions. It is important to note that the customer does not intend to specify “how to” but does expect the supplier to adequately define how they intend to control the processes that will produce a product that meets the customer’s performance requirements.

Manufacturing processes and their controls are an integral part of the development of hardware product. A cross-functional team¹⁵³ including a manufacturing representative is convened. The team responsibilities include contract reviews, customer requirements definition, conceptual design, and development of a Manufacturing Production Plan. The plan includes process Controls, Scheduling, Shop Orders, Visual Aides, Quality, Production Flow, Material Staging,

¹⁵² Organizational and Technical Interfaces BP Requirements Section 1

¹⁵³ See Section 1.0 Organizational and Technical Interfaces

Maintenance Plans, and Key Characteristics which may be affected during the manufacture process.

Manufacturing management conducts periodic reviews of operating systems performance metrics (par. 10.1.4.). Customer required manufacturing process audits and approvals are established and documented in a Program Control Plan. Commercial customer audits are typically conducted on an as-required basis; usually when one of the production or quality tracking metrics has fallen below an acceptable level. These metrics and control limits are usually established by the customer and mutually agreed upon by supplier. Process improvement objectives are mutually established and may consist of short term objectives such as the Upper Control Limits (UCL) or Lower Control Limits (LCL) for SPC controlled processes, and long term customer-mandated improvements in the production processes. Generally, no manufacturing process status reports are required by commercial customers (par. 10.2.1.).

Figure 10-1. Manufacturing Process Control Model illustrates a typical overview manufacturing process development timephased during a product life cycle. The red (dark) symbols indicate production control activities or reports that may be required by the customer. The yellow (light) shaded areas indicate activities that may involve the customer, specifically with cross-functional teams and with respect to the customer reviews

In this process the design team receives the customer performance requirements and begins the conceptual design. Cross-functional teams are established including the manufacturing representative to identify key characteristics and manufacturing processes that may affect them. Process development continues in parallel with the product detail design phase using design-of-experiments, prototype models, and product simulation. Manufacturing documentation is established for control plans, operator instructions and visual aides. All manufacturing documentation is reviewed at the Manufacturing Readiness Review (MRR) to ensure the customer that controls are in place to produce acceptable product. Final iterations of the manufacturing documentation are made during the product and process Validation just prior to release to production.

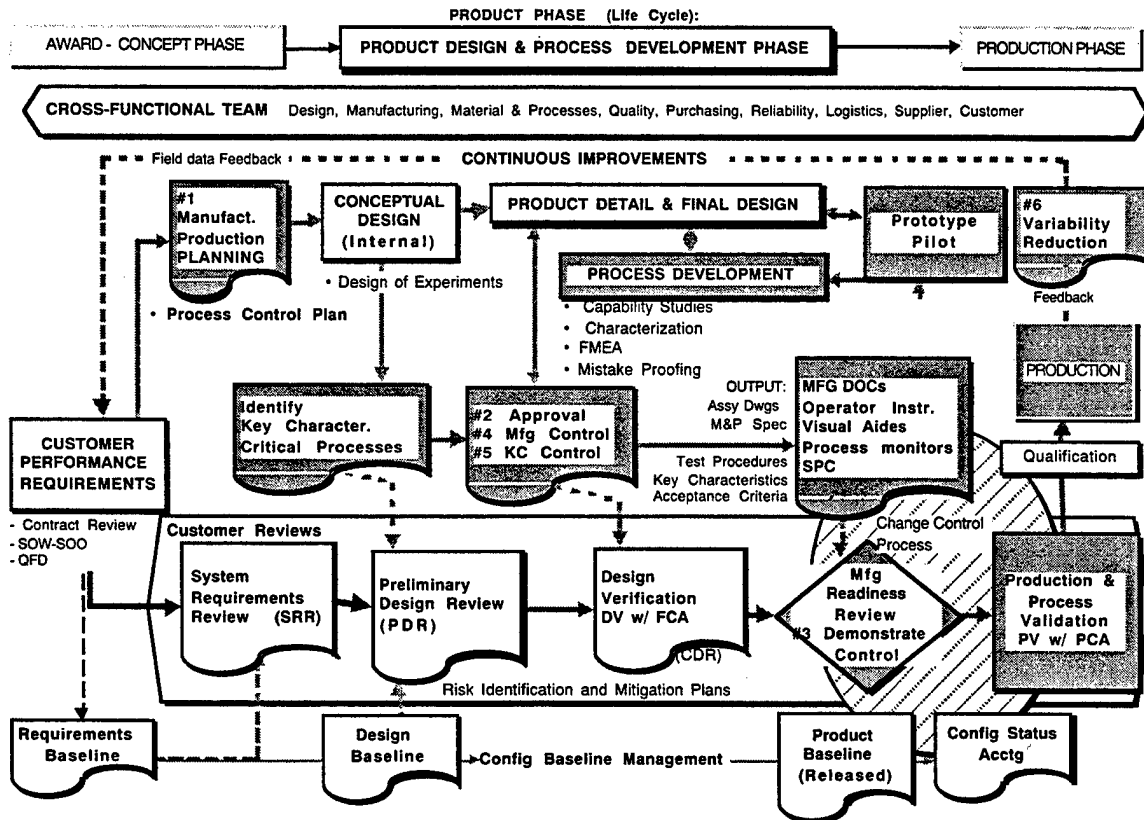


Figure 10-1. Manufacturing Process Control Model

10.1 Process and Control Best Practices

Manufacturing Process and Control best practices typically found in world-class companies are shown in Figure 2. This “fish-bone” or “cause and effects” figure depicts the contributor to product quality and customer satisfaction: (a) mangement, (b) manpower, (c) methods and controls, (d) materials, (e) machines, and (f) measurement and monitoring.

Management Practices

The supplier’s management answers the questions of Who, What, When, Where and How. The management function initiates the front-end planning and periodic performance reporting to company owners and customers. In addition to normal considerations for adequate budgets, compliance with Federal, State and Local Government Safety and Environmental Regulations¹⁵⁴, and with customers requirements, management must also provide (a) a suitable framework of documented procedures, instructions;¹⁵⁵ and workmanship criteria¹⁵⁶ (b) ample facilities for staging, fabrication, assembly, test, storage and shipping; (c) equipment¹⁵⁷ (machines and test

¹⁵⁴ ISO 9001-1994 Par. 4.9 (c)... compliance with reference standards/codes
QS9000 Par. 4.9 b: Compliance with government safety and environmental regulations

¹⁵⁵ ISO 9001-1994 Par. 4.9 (a)... documented procedures

¹⁵⁶ ISO 9001-1994 Par. 4.9 (f) ... criteria for workmanship

¹⁵⁷ ISO 9001-1994 Par. 4.9 (b)... use of suitable... equipment, and suitable working environment....

equipment) capable of producing the required dimensional tolerances or product finishes; (d) Electro Static Discharge (ESD) Controls, which may include conductive flooring, wrist and/or toe/heel straps, and climate control to reduce electronic discharge of components; and for (e) minimization of parts and product handling and flow.

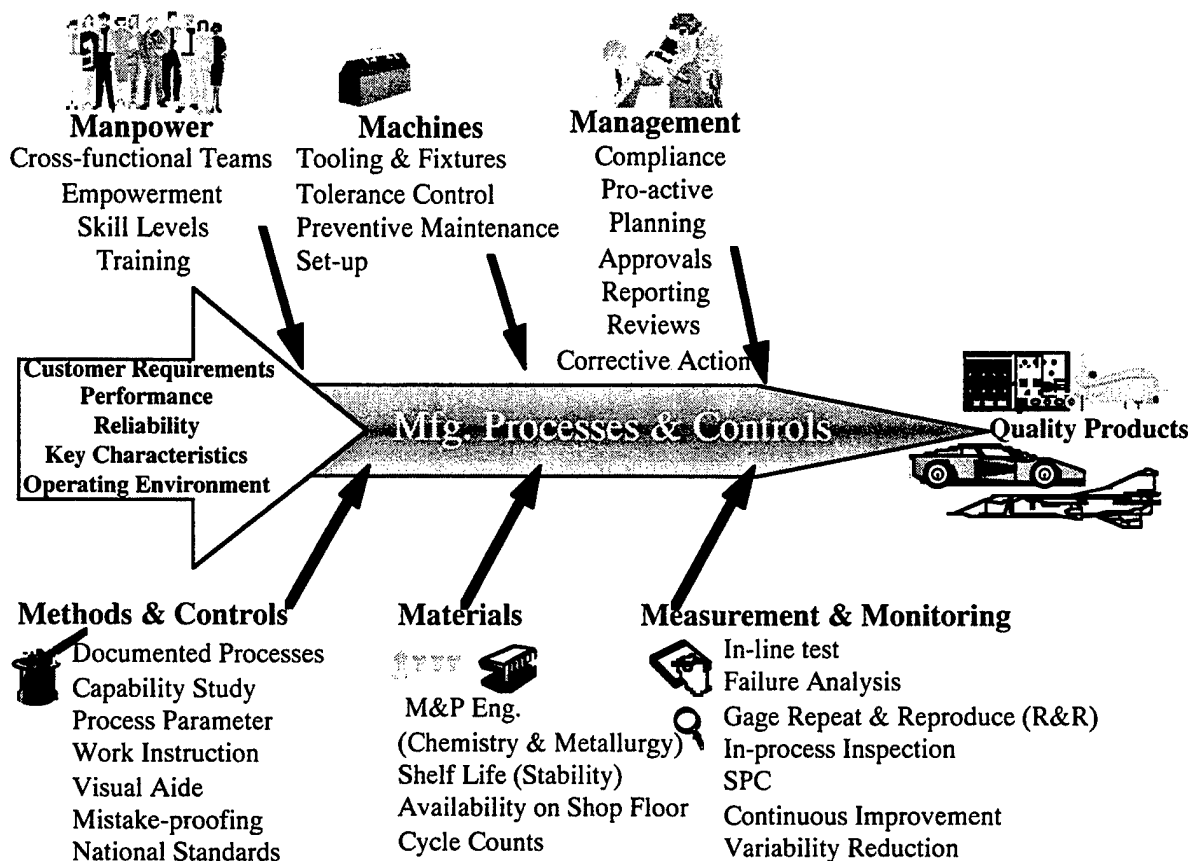


Figure 2. Manufacturing Process and Control Best Practices

10.1.1 Manufacturing Planning

Advanced planning by the manufacturing organization is the key to improving product yield by reduction of the causes for variation. Typical planning may include:

- Process Control Planning is a part of the overall production Plan.
- Capacity Planning determines manufacturer's ability to react to customer's long term needs.
- Material Planning includes the selection of compatible materials & components, and inventory controls to ensure that the correct material, which has been properly accepted for use, is available to production when and where required for subsequent operations.

The supplier should have process controls¹⁵⁸ in place to assure consistency in quality, reliability and performance of the product. Specific process controls depend on the type of product being produced. Where customer requirements cause the supplier to modify their processes, modified capability requirements should be documented in the Program Control Plan.

The supplier shall describe its internal manufacturing procedures, processes, standards, and tests which ensure that stated performance and reliability requirements will be satisfied.

When the supplier's existing process control systems and procedures do not adequately address a customer's requirements, a Process Control Plan¹⁵⁹ is developed to clearly describe the supplier's intended approach for compliance of the supplier's and sub-tier supplier's systems. This plan may be combined with the overall Program Control Plan and typically requires customer approval prior to implementation or for any changes to the plan.

The Process Control Plan consists, at a minimum, of the organization structure with defined roles and responsibilities and a written summary (listing) of applicable policies and procedures, national or Industry Standards being used and the following elements as applicable:

- Ultimately drives the quality of the product and should be based on the expectations of customers. Workmanship criteria is established, based on national Standards such as IPC-610 and ANSI J-STD-001, or supplier-developed criteria and must be adequately documented and communicated to all employees.
- Key product or special process characteristics
 - Identification of customer-identified Key Characteristics, usually indicated in the drawings or statement of objectives.
 - Identification of supplier-identified process special characteristics, used in manufacturing or assembly that may affect the product performance or requirements.
 - Minimum capability of each process parameter in the manufacturing process (Cpk) that may affect a product key characteristics or performance. (par. 10.1.4)
 - Key characteristics usually require 100% pass/fail, manual or electronic testing (see Appendix B - Special Characteristics Guideline).

¹⁵⁸ ISO 9001-1994 Par. 4.9 (d)... monitoring and control of suitable process parameters and product characteristics;
QS9000: Additions per Automotive Quality System Requirements designation, documentation and control of special characteristics.

- Par. 4.9.1 Process Monitoring and Operator Instructions
- Par. 4.9.2 Preliminary Process Capability Requirements
- Par. 4.9.3 Ongoing Process Performance Requirements
- Par. 4.9.4 Modified Capability Requirements (CONTROL PLAN)
- Par. 4.9.5 Verification of Job Set-ups
- Par. 4.9.6 Process Changes

¹⁵⁹ QS-9000 Par. 4.9.6 Modified Capability Requirements
PARTS MANAGEMENT AIAA R-100-1996, JUNE 1996 DRAFT PAR. 3.2.3.2

- Controls in place (inspection, test, sampling plans) during normal manufacture.
- Short term corrective actions to be taken should the process go out of control.
- Internal manufacturing practices that control foreign object damage to the product or subsequent installations.

10.1.2 Approval of Manufacturing or Assembly Processes

During the development and implementation of the manufacturing process, it is required that the supplier's management, together with the customer, establish process review points to assure a minimum risk to the customer and minimization of costs and labor incurred by the supplier through reduction of testing, inspection, rework, and scrap. Typically, these review points are during Manufacturing Readiness Review (MRR) and/or Production Validation (PV). These review points should be documented in the overall Program Control Plan.

The supplier shall establish process review points, notify the customer, and obtain approval¹⁶⁰ as required prior to any process changes that affect the product form, fit, function or interface requirements.

Note: Process changes involving the manufacturing engineer and the extent of the change affecting product form, fit, function or interface, may require Configuration/Change Control Board (CCB) approval.

10.1.3 Manpower Practices

This section is intended to illustrate some of the lean enterprise or best practices being used by world-class companies.

Manufacturing Personnel Involvement

The cross-functional team will evaluate and incorporate into the manufacturing planning as appropriate, the lessons learned in product and process development. Manufacturing representation on cross-functional teams is necessary from the design phase through the warranty period. Team activities may include the following.

- Design for Manufacturing or Assembly (DFM/A)
- Process Failure Mode and Effects Analysis (PFMEA)
- Risk Analysis for new materials and processes, or state-of-the-art designs
- Manufacturing and Process feasibility
- Design Failure Modes and Effects Analysis (DFMEA)
- Design Validation (DV)

¹⁶⁰ ISO 9001-1994 Par. 4.9 (e) ... approval of process and equipment, as appropriate...

- Manufacturing Readiness Review (MRR)
- Production Validation (PV)

Training and Certification

Optimization of the employee's capability is accomplished by training and employee certification. Any person having to do with product quality must be adequately trained by experience or education to perform their tasks. Training¹⁶¹ should include executive management, supervision, and technical personnel and should provide for the maximum utilization of personnel. A flexible workforce capable of performing a variety of tasks provides greater scheduling capability and the ability to move people from one area of expertise to another when illness, vacation or other manpower capacity restraints occur. Both training and rewards are necessary to establish a successful skill based work force. Some typical techniques follow.

- On-The-Job Training (OJT)
- Manufacturer classes for equipment operation
- Trade or technical schools
- Professional association certifications
- National aptitude tests
- Solder school
- Mechanical ability
- Skill development

Certification of employee skill levels to perform multiple duties, operate equipment, maintain equipment, and train others should be established. An operators re-certification is established at pre-determined intervals. A skill-based pay incentive programs may be established to incentivize the worker; the more tasks a person can perform in the company, the more pay they receive.

Operator Empowerment

Empowerment is a best practice that requires a supportive management style that encourages effective communication, training for improvement, establishes clear and attainable goals, and recognizes improvement behaviors. Employees should be empowered to correct or stop any process that receives or develops inferior product. These employees are often the best people to suggest process improvements.

10.1.4 Manufacturing Process Methods and Controls

Process Failure Mode and Effects Analysis (PFMEA) is a risk management process used to assess the level of control that is necessary on the manufacturing process either by redesign, mistake proofing, inspection and test, or to identify those areas of high risk to the product. All

¹⁶¹ ISO 9001-1994 Par. 4.18 - Training.

FMEA activity is to be completed prior to production. Any high volume process should seriously consider the use of PFMEAs.

Process Capability Cpk	Defects per Million w/ CENTERED PROCESS	SIGMA σ	
1.00	2700	3	Unstable Process. Below Requirements 100% Inspection Req'd
1.33	63	4	Non-complex part/assembly. Minimum Critical & Safety Characteristics
1.67	0.6	5	Critical & Safety Characteristics
2.00	0.002 2 parts / Billion	6	

Table 1. Cpk-PPM-Sigma Comparison

Processes Affecting Key Characteristics

All key characteristics should be addressed and identified in the Process Control Plan. Controls for key characteristics should be included in Process sheets (Work Orders and Routings). A Key Characteristic controlled by a manufacturing process requires to measure the capability and stability of the process during the manufacturing cycle. Process controls should remain in place until the process can sustain a minimum 1.33 Cpk.

Identification of process effects on the product

The supplier may use several different techniques to determine the effects of processing on the product and the end product characteristics. These techniques should be applied for the end product's key characteristics as well as the overall product performance requirements. Techniques include the following.

- Process Failure Mode and Effects Analysis (PFMEA)
- Assembly Build Variation Analysis simulates the buildup of an assembly and examines tolerance accumulation, statistical parameters, sensitivity.
- Characteristic Matrix displays the relationships between process parameters and manufacturing stations. and identifies the extent of manufacturing relationships to process parameters and the areas to apply controls for a given parameter.
- Design of Experiments¹⁶² (DOE) is a process to control and reduce the effect of manufacturing process variations on the end product.
- Cause and Effect Diagram also known as fishbone or Ishikawa diagrams is used to identify the cause of product variations.

¹⁶² Advanced Product Quality Planning and Control Plan Pg. 46, 82

The results of these techniques establishes the relationship between the end product key characteristics and performance requirements and those manufacturing process characteristics which affect the end product.

10.1.5 Process Capability Study

The process capability studies (also known as “process characterization”) address the ability of the manufacturing process to maintain control of the end product throughout manufacturing. Process capability studies (characterization) are required to ensure that the manufacturing process is capable of producing a product with the key characteristics under control. A process capability study determines the limits within which a tool or process operates and the statistical calculation of the variation between the process specifications and its actual performance. These studies help to define the level of control, test, and inspection necessary for each characteristic, both process and product, and are usually conducted during the equipment qualification and when equipment is initially setup or moved.

The following practices, determined during customer requirements reviews and engineering evaluations, may be used to establish a process capability. These practices require that the process be measured and tracked for trend analysis.

- Process flow charts
- Pre-qualification of material, equipment, Computer systems and software, procedures, personnel (operators), and manufacturing processes,¹⁶³
- Process capability index (Cpk) is determined with process parameters and control points.
- Part characteristics and process parameters are incorporated into control plan.
- Environmental issues affecting components and processes
- In-process inspection points.
- Design of Experiments

All processes affecting a critical or Key Characteristic shall require a Cpk=1.33. When these processes are less than 1.33, the supplier shall submit a plan and schedule for attaining a Cpk =1.33¹⁶⁴. The supplier may alternately choose to perform 100% in-process product inspections.

A statistically stable process output has an inherent variance within a range of 6σ (sigma). This is indicated by:

- Cp = The process variation relative to process/machine specification is known as Process Capability Index. $Cp = \text{Tolerance width} / \text{process capability}$.

¹⁶³ ISO 9004-1-1994 Par. 10.2 Process Capability

¹⁶⁴ QS-9000 Ford Specific Requirement, page 68

- Cpk = The process variation and centering relative to the specifications is known as Centered Process Capability Index. Relationship of the process mean and the specification limit.
- Ppk = The performance index which is compared with either Cp or Cpk and is used to prioritize process improvements over time.

A process capability index (Cp, Cpk) is defined as $\pm 3\sigma$ (6 standard deviation total = 6σ) spread of process measurements taken after the process has been characterized and is stabilized. A process with an output capability index (Cpk) of 1.33 will produce 63 defective parts per million.

Documentation of assembly instructions

Process control instructions are required to ensure that product quality and reliability are consistent. The manufacturing process control planning includes process flowcharts, manufacturing shop orders, and visual aides and should indicate, at the applicable operation, the key characteristic that may be affected by a particular operation or process with the necessary inspections, tests, or observations that must be made prior to continuing with the process. An automated process might require operator intervention to indicate that the proper controls have been completed, in order to continue in the process flow.

Mistake-proofing (Poka-Yoke)

- Definition: Mistake proofing¹⁶⁵ is the use of process or design features to prevent manufacture of nonconforming product. When potential sources of nonconforming product are identified by FMEAs, capability studies and field reports, these sources shall be addressed using mistake proofing methodology during the planning of processes, facilities, equipment and tooling.

Mistake-proofing techniques within the process reduce opportunity for human or machine error by use of simple devices used to detect or avoid defects such as checklists, guide pins, tooling holes, counters to ensure correct number of parts or cycles processed, limit switches (go-no-go), or more sophisticated automation of manufacturing operations, alarms for automated in-process testing, and finally a manual inspection performed as an automatic part of the manufacturing process.

10.1.6 Manufacturing Material Compatibility with Product

It is the responsibility of the materials and processes engineering activity to develop, select, and implement materials and processes that are cost effective and compatible with the product being manufactured. Much of this activity occurs during the design and process development cycle. Additionally, dedicated process engineers may be responsible to support common processes

¹⁶⁵ QS9000 Pg. 55

across a variety of products. A best practice found in both defense and commercial industry is the control and verification prior to use in manufacturing or re-certification, for material that is subject to deterioration as a result of exposure to the environment (air, heat, light, or moisture), or has limited shelf life in storage or after mixing. These controls or practices may include the following.

- Storage and labeling of material in a controlled environment
- Date for material is adequately documented and displayed expiration
- Effective recall system for material either with or nearing expired shelf life.
- Prohibition of material with expired shelf life for use in production
- Dry storage and moisture bake-out of circuit boards prior to assembly.
- Proper curing time during assembly. "start time" and "end time" may be recorded in the shop control documentation or computer system for the applicable operation.

Examples of such manufacturing materials and processes include:

Materials	Processes
solder	soldering
fluxes	cleaning
adhesives	material dispensing
conformal coatings	stencil printing
printed wiring laminate	conformal coating
printed wiring finishes	adhesive bonding
	lead forming
	tinning
	shelf life re-certification

10.1.7 Machine Suitability, Verification and Maintenance

Perform Tooling Verification

Evaluation of new tools or gages. New tooling may be tested at the tool supplier prior to delivery to determine its capability (P_{pk}) and then again after the tool has been installed in the production flow. Manufacturing engineers should conduct pre-qualification product builds to ensure that the machine or process tolerances are being maintained.

- Ref. 10.1.5 Process Capability Study (par. 10.1.5).

Verification of Job Set-ups

Verification of a set-up is necessary to ensure successful processing. Methods of verification that should be available to the operator, may include the following.

- Instructions for each machine or process including parameters
- Setup Procedures

- Set-up verification at start of each shift by visually inspecting first piece through the process
- Visual aides or graphics picturing the assembly or characteristic
- Workmanship standards
- Training requirements
- Labeling of kits, board assembly panels, process controls
- Machine-readable bar-code or dot-matrix labels affixed to sub assembly panels during manufacture. These labels, together with Computer Integrated Manufacturing (CIM) systems are capable of ensuring that the proper part is selected and inserted into the panel, and detecting missing or wrong components installed in a location (reference designator) .
(Note: The bar-code label may not be appropriate for all processes or for processes that are not controlled by automation).

In-process Verification

Each process-owner should inspect their own work to ensure that inferior product is not sent to the next operation. First piece inspection is particularly important when there is a line set-up or change of shift. On-going observation of the assembly process and random sampling products will ensure that acceptable product is forwarded to the next operation.

Establish Preventive Maintenance Program

A maintenance¹⁶⁶ program with periodic recall is necessary for key process equipment. Most maintenance programs are based on manufacturer's recommendations but may require tailoring as appropriate for the particular application and constraints.

10.1.8 Process Monitoring

Process monitoring may take many forms and the supplier should determine what is appropriate for their products and describe the process monitoring program in their Manufacturing Control Plan. Some of the major monitoring techniques include the following.

- • Process Failure Modes and Effects (PFMEA)
- • Automated in-line testing, in-process inspection by manufacturing personnel, not QA
- • SPC require selection of statistical tools¹⁶⁷ and knowledge of basic statistical concepts
- • Continuous improvements to design guidelines and processes is an ongoing effort process and product measurement and trend analysis.

¹⁶⁶ ISO 9001-1994 Par. 4.9 (g) suitable of equipment...

QS9000 Par. 4.9: ... scheduled maintenance, and predictive maintenance methods for key process equipment

¹⁶⁷ ISO 9001-1994 Par. 4.20 Statistical Techniques

Measurement (Gages)

Many calibration standards exist for gage repeatability and reproducibility (R&R). Equipment used for product inspection and acceptance must be controlled, calibrated, and maintained with reference to a national standard¹⁶⁸. The supplier should describe their gage R&R (calibration) program in their Manufacturing Control Plan. The key requirement for gage R&R are that the equipment is scheduled for verification of accuracy (calibration) and is tagged with expiration date for effective recall.

Note: MIL-STD-45662 Calibration has been CANCELED 2/95. Possible replacement is ANSI/NCSL Z-540.1 or ISO 10012

10.2 Operational and Process Control Reporting

Management reporting¹⁶⁹ includes periodic information that is provided to the supplier's internal management. The reports or presentations are generally considered to be competition sensitive and may include the following general operational metrics.

- Shipments vs. schedule: On-time delivery to the external customer
- Sub-tier supplier performance: On-time deliveries and quality of products and the use of past performance data in future sourcing decisions
- Process yields by product or by product line
- Inspection results including deviations and corrective actions
- Scrap, rework, repair costs
- Warranty claims or customer returns
- Labor or process efficiency metrics
- Evidence of SPC results in management decisions
- Results of internal audits and status of any necessary corrective actions

10.2.1 Reporting Process Controls and Improvements

External reporting is usually not provided by commercial suppliers. Occasionally customers will require, on an exception basis, very high level reports depicting the control history for a specific process that is related to their products. These reports should be in the supplier's existing format. Typical examples of reports that may be required include:

- Progress made towards mutually established process capability or continuous improvement goals,
- Results of corrective actions related to customer products

¹⁶⁸ ISO 9001-1994 Par. 4.11 Control of Inspection, Measuring, and Test Equipment

¹⁶⁹ ISO 9001-1994 Par. 4.1.2.3 "... reporting on the performance of the quality system to the supplier's management ..."

QS9000 Pg. 65 - AEN/Ford Quality Operating System (QOS)

- Documentation showing compliance with customer requirements for control of key characteristics,
- SPC reports for processes controlling product key characteristics and,
- Cost-of-quality reports (Ref. Quality Systems Section 5 “.. internal management reporting and trend analysis”).

The supplier shall provide Process Controls reports on an exception basis, as specified in the contract or Statement of Objectives.

CAUTION: Requirements for SPC reports or Cost-of Quality reports are NOT commercial practices and may preclude contracting with commercial suppliers. Reports which contain “competition sensitive” information or require additional reporting systems must be mutually agreed upon. The content and frequency of all reports should be clearly defined in the contract or statement of objectives and in the supplier’s program control plan.

10.3 Demonstrations of Operational Controls

During the supplier selection or product/process development cycles, customers may wish to have a demonstration of the process controls and internal management interfaces that are routinely used in the facility. Demonstrations for selection by a customer may require evidence to the customer business control metrics, manufacturing SPC control charts, or other trend analysis demonstrations for processes controlling product key characteristics. When the customer is a member of the cross-functional team, many of these reports would not be required.

The supplier shall provide operational and process capability demonstrations to the customer as specified in the contract or Statement of Objectives.

10.4 Variance Reduction Program

Variation of key product characteristics¹⁷⁰ or key process parameters will eventually cause defects that go undetected until a subsequent operation resulting in a decreased product quality and increased product costs caused by rework, repair or scrap. Variance Reduction Program (VRP) is a continuous improvement best practice that relates specifically to design, manufacturing, assembly and test of the product. VRP is established prior to any processing activity, to improve product performance, reliability, cost, and reduction of manufacturing cycle times by identification of customer or supplier key characteristics (Kcs), reduction of process variation through the use of statistical tools, special test equipment, computer-aided manufacturing,¹⁷¹ operator instructions, and implementation of other value-added techniques.

¹⁷⁰ Ref. IBP Handbook Appendix B - Key Characteristics

¹⁷¹ Ref. <http://www.bmpcoe.com> Expert Systems for Reducing Risk

10.4.1 Variability Reduction Instructions

Variability Reduction Instructions (VRI) for each customer-specified Key Characteristic are referenced on the defense customer's product drawings, or included in the design documentation, re-procurement package or producibility plan. The VRI records the frequency of process interaction, observation or tracking technique and any documentation required to be completed at each process control point. All key characteristics must be designated using mutually agreed upon symbols by the supplier and customer.

The commercial supplier imbeds these special instructions into their process failure mode and effects analysis and work orders or process instructions. Unique operation numbers are assigned to processes requiring special control points and methods. These instructions are available to each operator as necessary and may include the following major headings.

- Process/inspection guidelines
- Control /critical parameters
- Setup/shutdown procedures
- Training requirements
- Trouble-shooting
- Process control table and flow chart
- Visual aides

Variability Reduction Instructions shall be included in manufacturing instructions or other process control documents which emphasize the control of Key Characteristics.

CAUTION: The linkage of a key characteristic on the customers drawing to a Variability Reduction Instruction in the suppliers manufacturing documentation is not available with commercial suppliers. Their process control plan and instructions should adequately identify each key characteristic and the method of control, standard used, and frequency of monitoring. The intent of the VRI will be met, but not the document linkage. The VRI information is not provided to the customer.

10.5 References

INTERNET ACCESS REFERENCES in Appendix C

10.6 Attachment A - Military Specifications Affecting Manufacturing

For reference only. This table provides process control standard's status as of 1Q97 and may not be all inclusive.

DOCUMENT	TITLE	STATUS
DoD-HDBK- 265	ESD CONTROL PROGRAM	CANCELED (11/89) S/S MIL-STD-1364 Canceled 4/95 no S/S <i>Note:</i> See DoD-HDBK-263 (7/94) MIL-STD-1686 (10/95)
DoD-STD- 1686 (See MIL-STD-1686 in 5PTA3242)	Document exists only as reference in data base (DODISS)	Replace with DoD-HDBK-263 8/8/96 Future acquisitions refer to MIL-STD-498 10/95: Converted to Standard Practice MIL-STD-1686C. 4/19/95 OSD/DSIC: Convert MIL-STD-1686B to standard practice nlt 12/95.
MIL-C-28809	CIRCUIT CARD ASSEMBLY	CANCELED 4/21/95 DODISS OSD/DSIC Canceled by NOTICE 1 w/o Replacement
MIL-I- 8700A (2/92)	Installation and Test of Electronic Equipment in Aircraft	3/98 Active DODISS Ref: IPC-610 Ref: ANSI J-STD-001
MIL-P-11268L (3/97)	PARTS, MATERIAL & PROCESSES	3/98 Active DODISS 12/95: SPO - DELETE contract reference
MIL-PRF-55110F (5/97)	PRINTED WIRING BOARD, GENERAL SPEC	3/98 Active DODISS MIL-P-55110 Replace w/ National Standard IPC-D-275 and IPC-RB-276 1/29/96: DODISS: QPL-55110-44, dated 9/26/95, PRINTED WIRING BOARD, RIGID, GENERAL SPEC. 4/19/95 OSD/DSIC: Convert to PRF Spec by 10/95 Misc. REF: ANSI/IPC-600D, IPC-RB-276, IPC-D-275 ISO 9100 IPC 610 IPC 900
MIL-S-45743E	SOLDERING, MANUAL TYPE, HIGH REL.	CANCELED 2/27/95 OSD/DSIC by NOTICE 2, Refer to MIL-STD-2000A 9/8/89 DODISS: Inactive
MIL-S-46844C	SOLDER BATH soldering of PWA	CANCELED 2/27/95 DODISS OSD/DSIC by Notice 2, Superseded by MIL-STD-2000A.
MIL-S-46860B	SOLDERING OF METALLIC Ribbon Lead Material to terminal	CANCELED 2/27/95 DODISS OSD/DSIC BY NOTICE 2, Refer to MIL-STD-2000A
MIL-STD- 410	NONDESTRUCTIVE TESTING PERSONNEL & CERTIFICATION	CANCELED 12/31/97 DODISS S/S NAS 410

DOCUMENT	TITLE	STATUS
MIL-HDBK- 454 (5/28/97)	ELECTRONIC EQUIPMENT, STANDARD GENERAL GUIDELINES	MIL-STD-454M CANCELED 5/28/97 Replaced with Handbook. Replace w/ National Standard Ref. IPC-610 Ref. ANSI-J-STD-001 5/4/95 DODISS: Superseded by MIL-HDBK- 454 2/1/95: OSD/DSIC Cancel w/o Replacement after issuance of HDBK.
MIL-STD- 980	FOREIGN OBJECT DAMAGE PREVENTION	CANCELED 11/295 by Notice 1 NO S/S 6/7/95 OSD/DSIC: CANCEL Redesignate as HANDBOOK
MIL-STD- 1528A	MANUFACTURING MANAGEMENT PROGRAM	CANCELED 2/27/98 NO S/S Air Force EXEMPTION GRANTED
MIL-STD- 1567A	WORK MEASUREMENT	CANCELED 2/27/95 NO S/S Ref. ANSI/ASQC Q9004-1-1994 6.2.2
MIL-STD- 1568B	M&P FOR CORROSION PREVENTION	CANCELED 2/6/96 DODISS Possible NGS
MIL-STD- 1595A (7/30/87)	QUAL OF FUSION WELDERS	3/98 ACTIVE DOSISS 5/3/95: RETAIN until NGS available from AMER. WELDING SOCIETY Draft ECD 11/96. ECD: 6/30/97
MIL-STD- 1686C (10/25/95) See also: DoD-STD-1686	ELECTROSTATIC DISCHARGE (ESD) CONTROL PROGRAM	3/98 ACTIVE DODISS 8/8/96: ASTM writing NGS 10/25/95 Converted to Standard Practice: MIL-STD-1686C 04/19/95 OSD/DSIC: Convert to Standard Practice NLT 12/95.
MIL-STD- 1840C (6/24/97)	EDI interchange	6/26/97 DODISS Designated as Interface Standard
MIL-STD- 2000A	SOLDERED ELECTRICAL & ELECTRONIC ASSEMBLY, REQUIREMENTS FOR	CANCELED 6/7/95 OSD/DSIC by NOTICE 1 w/o Replacement; future acquisitions shall not cite a soldering process requirement. Replace w/ National Standard Ref. NGS: IPC 610 Ref. ANSI J-STD 001 thru 006
MIL-STD-45662 A	METROLOGY (CALIBRATION)	CANCELED 2/27/95 OSD/DSIC: by NOTICE 2 Replace w/ National Standard ISO 10012-1 or ANSI NCSL Z-540-1
MIL-STD-45743	Soldering Manual Type High Reliability	CANCELED 2/95
MIL-STD-46844	Solder Bath	CANCELED 2/95 Refer to MIL-STD-2000
MIL-STD-46860	Soldering of Metallic Ribbon Lead	CANCELED Refer to MIL-STD-2000

11. Product Support and Logistics

Objective: Ensure continuity of supply, replacement, maintenance, and product warranty for the post-delivery product life cycle.

The purpose of this document is to establish basic requirements for evaluation of a supplier ability to plan for and provide post-delivery product support or logistics, to distinguish the functions provided by a product supplier from the customer's internal system-level logistics functions, and to ensure that the needs of both buyer and seller are satisfied.

- Definition: Traditional "logistics" is defined by Webster as "the branch of military science concerned with the procurement, transportation, maintenance, and supply of troops, equipment, and facilities."

The military definition typically addresses logistics support for a defense system but, the lower-tier supplier logistics support requirements apply only to a product. As the supplier-tier moves closer to the ultimate system-level customer the logistic support requirements increase. "Product support" is used in this document to discuss logistics requirements and represents the more commercial terminology at the product level.

The requirements developed in this document are only applicable when specified in the contract, statement of work or operational requirements matrix¹⁷². The supplier's own systems or processes must meet the intent of these requirements. The requirements for policies and/or procedures are shown below.

Requirement Title	Par.
• 1. 11.2 Product Support Plan	11.2
• 2. 11.3 Transferable Technical Data Package	11.3

Figure 11-1. Product Support Program Model, illustrates the interaction of the product support requirements with design and parts control activities through the production cycle. The product support plan addresses four key elements: (1) re-procurement information, (2) technical documentation necessary to build the product, (3) warranty, repair and maintenance requirements, and (4) recommendations for product improvement during the life cycle.

¹⁷² Organizational and Technical Interfaces BP Requirements Section 1

11.1 Product Support Model

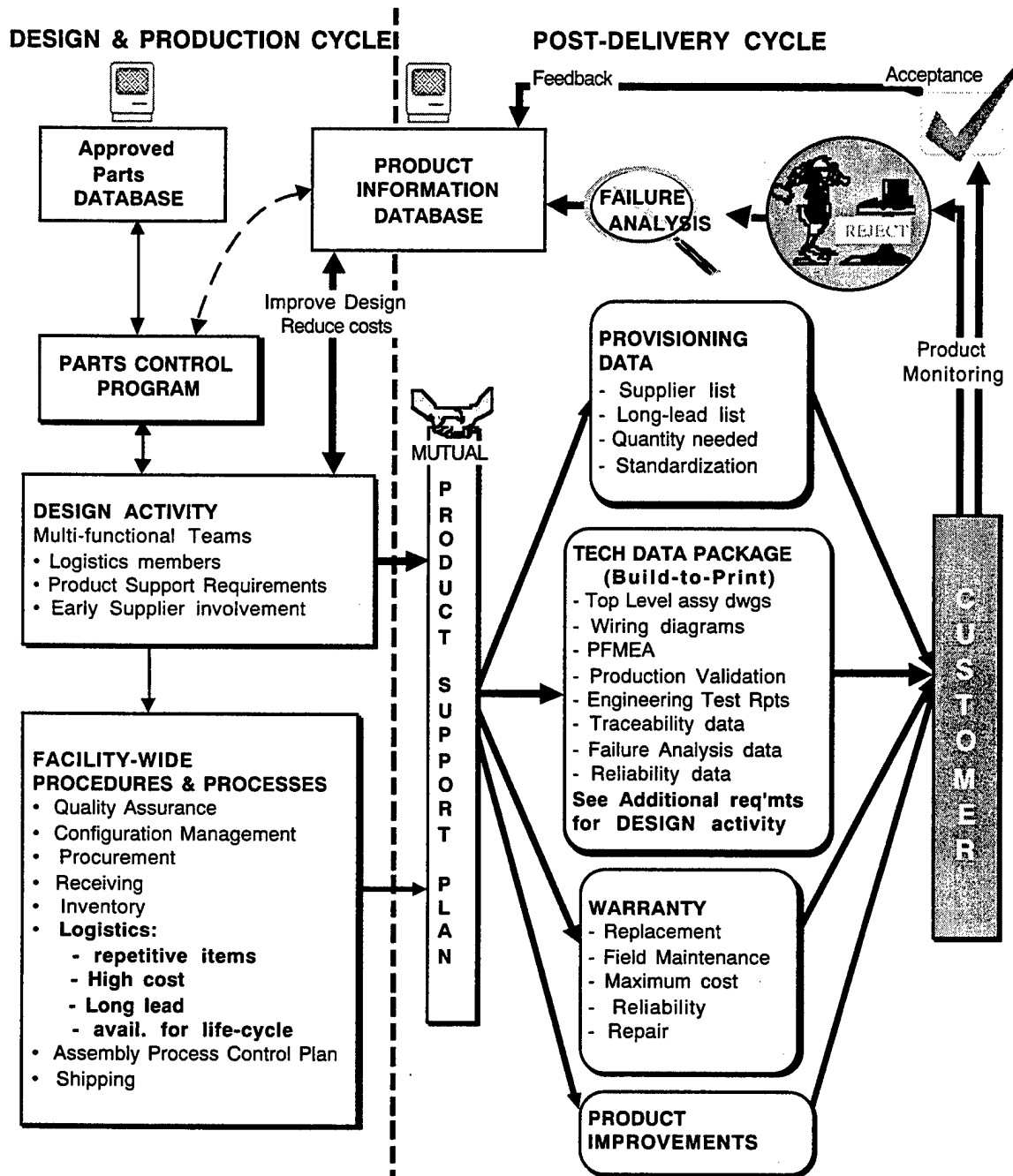


Figure 11-1. Product Support Program Model

Background

Logistics requirements for both defense and product support practices for commercial companies have the same basic purpose — to ensure that products are supported in a timely cost effective manner and to ensure continuity of supply. One reason for the increased importance attributed to logistics requirements in defense systems is the system life-cycle, which is usually much longer for defense products.

Market	Design Cycle	Production Cycle	Product Life Cycle
Personal Computers	3 - 6 mos	3 - 9 mos	3 - 8 yrs
Consumer Electronics	6 - 18 mos	3 - 12 mos	3 - 8 yrs
Automotive	2 - 3 yrs	1 yr	7 - 10 yrs
Defense System	3 - 8 yrs	<1 - 20+ yrs	> 20 yrs

Table 11-1. Typical Product Life Cycles - Electronics

The typical contract for Contractor Logistics Support (CLS), may require a combination of manpower or personnel to operate and maintain a product/system, support equipment required for operation or maintenance, operator or maintenance training support equipment for customer personnel, computer resources, and facilities for training or depot repairs and maintenance.

A commercial product supplier is typically expected to provide design interface for logistics-related requirements such as product maintainability, recommendation of parts and quantities for spares, warranty support including replacement, maintenance, and repairs for the product life cycle.

11.2 Product Support Plan

When the supplier's existing product support systems and procedures do not adequately address a customer requirements, a Product Support Plan is developed in sufficient detail to clearly describe the supplier's organization and intended approach for compliance with the customer's requirements. Mutually agreed upon requirements¹⁷³ and procedures are documented and may be combined with the overall Program Control Plan. The plan typically requires customer approval prior to implementation or for any changes affecting the intent of the plan.

A best practice to facilitate first-pass success is the establishment of cross-functional teams¹⁷⁴ that include product support personnel. The team ensures that product support requirements are addressed at the point where they can influence the economic balance between product cost, schedule, performance and supportability. Inclusion of the sub-tier suppliers in development of

¹⁷³ ISO 9004-1-1994 Par. 16.4.3, 16.4.4 Postproduction Activities: Servicing

¹⁷⁴ See Section 1.0 Organizational and Technical Interfaces

new products and their related support plans is critical to ensure that products will be supported in the most cost effective manner.

The supplier shall establish, document and submit for customer approval, a Product Support Plan¹⁷⁵ to ensure continuity of supply during the product life-cycle or as stated in the contract.

A typical Product Support Plan should describe the supplier's internal controls:

- Policies and procedures, national or industry standards used
- Organization structure with defined roles and responsibilities including cross-functional teams, with a description of core and out-sourced capability. Logistics must be an integral part of system requirements definition and design activities including participation in functional requirements review, contributing to design alternatives, product updates/improvements and identification of Key Characteristics, and other value-added analysis. In light of the "out-of-production parts" problems that plague most products, it may be beneficial to establish a parts control program during the product life cycle.
- Flexible warranty provisions to reduce product support costs and establish alternate support plan in the event of sub-tier supplier default.
- Supportability requirements¹⁷⁶ are defined with customers and comprise documentation of requirements for post-delivery support, provisioning (re-procurement) data including long-lead procurement lists, recommended inventory or spares quantities, recommend maintenance program, and identification of hazardous materials, pollutants, etc. associated with product bills-of-material or production processes.
- Technical or proprietary data which may be supplied with less than unlimited rights.
- Product information retrieval system to gather production issues during the manufacturing process as well as the customer's performance experience or field returns.

Note: The DoD is a leading proponent of CALS, or Computer-aided Logistics Support. This effort is aimed at implementing a core strategy to share integrated digital product data. Suppliers who demonstrate knowledge and/or implementation of the CALS standards are in a good position to satisfy the needs of military buyers for technical data.

11.3 Transferable Technical Data Package

The supplier shall provide a Technical Data Package in a format mutually agreed upon.

Technical Data Package include sufficient information as shown in Table 2, to allow the customer to provide adequate maintenance, repairs, and re-procurement of the product. Proprietary

¹⁷⁵ ISO 9004-1-1994 Par. 16.4.3, 16.4.4 Postproduction Activities

¹⁷⁶ ISO 9004-1-1994 Par. 16.4.3, 16.4.4 Postproduction Activities: Servicing

processes unique to this product or patented product may be included in this data package. However, the customer agrees to restrict the use technical data provided by the supplier, to product support requirements only. The data will not be provided to third parties without the written permission of the supplier.

DESIGN RESPONSIBILITY	BUILD-TO-PRINT ONLY
Top Level Drawings	Quality Assurance Plan
Module Drawings including Bills-of-Material	Configuration Management Plan Class 1 F ³ I changes (form, fit, function, interface)
Interface Design document	Parts Control Program Plan
Parts Control Program Plan* establish Preferred Parts Lists	Sub-Tier supplier test plan
Design Validation Plan & Reports	Process failure mode effects analysis (PFMEA)
Design failure mode effects analysis (DFMEA)	ESS Plan include Procedures
Engineering Test Procedures & Reports	Process Control Plan
Thermal Analysis	Product Support (Logistics) Plan
Corrosion Prevention & Control	Production Validation Plan & Reports
Test Failure Reports	Failure Analysis Reports - internal testing & field failures
Reliability Analysis	Repair Procedures
Human Engineering document	Reliability Analysis
Acceptance Criteria	Traceability data
Key Characteristics	

Table 2. Typical Technical Data Package Content

11.4 Product Support Best Practices

11.4.1 Parts, Materials, and process selection program

The supplier should have a facility-wide documented parts, material, and process control program for the selection and use of parts, materials, and processes in the design and manufacturing of the products. See Section 3.0 Parts Control Program.

11.4.2 Core Product Support Capability vs. Out-Sourcing Non-Core Functions

Suppliers who are capable of providing comprehensive product support have performed the economic analysis necessary to identify those product support functions that are best performed in-house vs. those that should be out-sourced to third parties. The supplier should be prepared to demonstrate that they have implemented the core focus policy and procedures and third-party agreements necessary to provide value-added product support.

11.4.3 Flexible Product Warranty Provisions

Suppliers with experience at providing product support typically offer flexible warranty provisions or options to help customers reduce their product support costs. Among the options that may be available are reliability improvement warranty, pre-paid upgrade provisions, and maximum cost-to-repair guaranty. The supplier and customer should mutually determine the most effective warranty options for product life-cycle requirements.

11.5 REFERENCES

Government Documents

- 1) The DoD regulatory cost premium: a quantitative assessment - Coopers & Lybrand/TASC December 1994
- 2) Improving the combat edge through out-sourcing - a report from DoD to Congress as part of the 1996 Defense Authorization bill, March 1996
- 3) Policy regarding performance of depot-level maintenance and repair - a report from DoD to Congress as part of the 1996 Defense Authorization bill, March 1996
- 4) Depot-level maintenance and repair workload - a report from DoD to Congress as part of the 1996 Defense Authorization bill, March 1996
- 5) SD-2 Commercial and non-developmental item handbook - Office of the Undersecretary of Defense for Acquisition and Technology
- 6) CALS executive overview
- 7) DoD Logistics Strategic Plan (2nd issue, 1995)

Other Sources

- 1) Proceedings from Diminishing Manufacturing Sources and Material Shortages conference May 1996, Houston, TX
 - Parts Management Best Practices, J. Korn, Lockheed Missiles & Electronics
 - Understanding the Causes of DMS, J. Martin
 - The Semiconductor Perspective, R. Kroeger, TI Military Products
- 2) Boeing Commercial Avionics Systems (CAS) Electrical/Electronics/Electromechanical Parts Control Operating Plan
- 3) World Airlines Suppliers Guide, Air Transport Association, 1994

12. Reliability

Objective: To affect product warranty and customer satisfaction

This requirements document was developed with the cooperation of commercial industry and defense contractors, to establish the agreed upon requirements for “best competitive” reliability practices. The contractor’s own processes or systems must meet the intent of these requirements. Performance-based product reliability requirements are contained in the product specifications.

Electronic hardware frequently requires software in order to perform its function. Software is addressed briefly in 12.12 Software Reliability Overview (par. 12.12). This section is focused on hardware requirements. National standards or reference documents are also referenced in 12.11 Military Reliability & Maintainability Standardization Documents (par. 12.11).

- Definitions: Reliability
 - per Webster: “suitable or fit to be relied on” or “giving the same result on successive trials”
 - per Reliability Analysis Center: “The probability that an item will perform its intended function under stated conditions, for either a specified interval or over its useful life.”
 - per MIL-HDBK-470A (8/4/97) - Maintainability Handbook: “The duration or probability of failure-free performance under stated conditions. The probability that an item can perform its intended function for a specified interval under stated conditions.”
 - Definition: Durability.¹⁷⁷ The probability that an item will continue to function at customer expectation levels, at the useful life without requiring overhaul or rebuild due to wear out.
 - Definition: Reliability Engineering: The technical discipline of controlling and managing the probability that a product will perform its intended function, in a defined environment (temperature, vibration, humidity, etc.), over a specified period, expressed in operational or storage time or cycles.

The requirements developed in this document are only applicable when specified in the Contract, Statement of Work or Operational Requirements Matrix¹⁷⁸. The supplier’s own systems or processes must meet the intent of these requirements. The requirements for policies and/or procedures are shown below.

Requirement Title	Par.
• 12.8 Product Reliability Program.....	12.8

¹⁷⁷ (AIAG) ADVANCED PRODUCT QUALITY PLANNING AND CONTROL PLAN (APQP) Pg. 103

¹⁷⁸ Organizational and Technical Interfaces BP Requirements Section 1

- • 12.9 Failure Reporting 12.9

Background

12.1 Reliability Standards and Reference Documents

This Business Practices Manual does not intend to specify any particular national standard; the supplier may use any national standard, reference document, or develop their own practices for their reliability program. The military specification reforms initiated by the Secretary of Defense, Dr. William Perry's policy memo of 6/29/94, resulted in many military documents being deleted or converted to handbooks.

The following listing of non U.S. DoD reliability standards is provided for informational purposes only.

- 1) CAN/CSA -Q632-90 -Reliability and Maintainability Management Guidelines, 1990
- 2) EIA/JEDEC JEP 70 - Quality and Reliability Standards, 1993
- 3) ANSI/AIAA R-013, Recommended Practice - Software Reliability, 1992
- 4) IEC 300-1, Dependability Management - Part 1: Dependability Programme Management
- 5) NATO ARMP-1, NATO Requirements for R&M
- 6) NASA NHB 5300.4 (1A-1) Reliability Program Requirements for Aeronautical and Space System Contractors
- 7) IEEE Reliability Program Standards #P1332 (Estimated release 2Q97)
- 8) SAE Reliability Program Standard #J2335 (Estimated release 2Q97)
- 9) Further information relative to world-wide R & M standards can be found in RL-TR-97-TBD, "A Primer for International Reliability and Maintainability Standards"

The following guidance documents were developed by the Reliability Analysis Center (RAC), a DoD Information Analysis Center managed by Rome Laboratory and operated by IITRI.

NOTE: USAF ROME LABORATORY References documents may be available through the Defense Technology Information Center (DTIC). Rome Laboratory Reliability Analysis Center functions have been cancelled as of late 1997. No replacement is available.

- "Blueprints for Product ReliabilityU." A series of documents published by the RAC to provide insight into, and guidance in applying, sound reliability practices. The blueprints are designed for use in both the government and private sectors. They address products ranging from new commercial consumer products to highly specialized military systems. The blueprints are not a cookbook of reliability activities that should be applied in every situation. Instead, some general principles of a sound reliability program are cited as the basis for tailoring a reliability program to best meet both the supplier's and the customer's needs. The blueprint approaches and procedures are based on best practices used by commercial industry and on concepts documented in many of the now-rescinded military

standards.

- Reliability Toolkit: Commercial Practices Edition - This tool kit is intended to help both commercial and military sectors deal with developing and manufacturing reliable products and concentrates on activities that have payoff, not necessarily extensive (and expensive) paper outputs.
- Commercial Parts and Processes for Military Applications- Intended to help bridge the gap between the use of military specifications and standards and acquisition reform in acquiring military systems or equipment.

12.1.1 Determination of Reliability Requirements

The most notable reliability distinction between defense and commercial acquisitions is *who* determines the reliability requirements and *when* reliability requirements are addressed.

There are many different levels of customer reliability requirements.

- The defense customer (DoD) is often acquiring a state-of-the-art, high cost systems that require high reliability during an exceptionally long life cycle. Because they pay a premium for higher levels of reliability; they establish the reliability requirements¹⁷⁹. Due to the high acquisition and maintenance costs of defense products, defense contractors spend much time and effort during product development (parts selection, modeling and DOEs) to ensure that the ultimate product will perform according to the customer requirements at the lowest life cycle cost and perform demonstration tests to confirm their reliability design objectives.
- Commercial customers typically state reliability requirements as performance objectives or goals, not specific reliability requirements or activities, and rely on the supplier to determine their product reliability, durability and/or warranty positions. Demonstration testing (reliability qualification testing) is usually not done¹⁸⁰ in these commercial suppliers; however, ample development and production test data should be available to the customer during product demonstration.
- The automotive customer, with a high volume of lower cost products, will mutually define the product performance requirements with the supplier, including the application and operational environment that the product will be exposed to over its life expectancy. The customer typically states in engineering specifications the reliability, confidence level, and tests to be performed by the supplier throughout the product development and production stages. The supplier may be required to repeat these tests annually. Some engineering specification tests (i.e. burn-in, final test, in circuit test) may be required on 100% of the product manufactured. Developmental testing is often combined with manufacturing test and field performance data to provide a demonstrated confidence in the initial reliability prediction.
- Airline suppliers establish reliability requirements that are developed with the final airline

¹⁷⁹ Ref. Reliability Toolkit: Pg. 47 Performance-based Requirements

¹⁸⁰ Benchmarking Commercial Reliability Practices, Pg. 22 Par. 3.6 (2)

customer. As an example, Boeing Commercial Aircraft Systems (CAS) will track all hardware failures during flight test to establish any product reliability trends. CAS is developing a reliability enhancement program consisting of tests¹⁸¹ that will mature the hardware prior to delivery to the airlines.

12.2 Reliability Activities and Processes

Table 1. Most Value-Added Reliability Activities, was developed from survey data obtained in the Benchmarking Commercial Reliability Practices¹⁸² by the Reliability Analysis Center. The two columns show the percentage of survey respondents that conduct reliability activities during design and development or during production.

Definitions of these activities may be found in various national standards and other reference documents. Design Reviews, Design of Experiment (par. 12.8.2), Subcontractor (selection) Control, and Parts Control are discussed in other areas of this Business Practices Manual.

Reliability Activities Most Value-Added Sequence	% Used @ Development	% Used @ Production
1 Predictions -Simulation -Modeling	91	12
2 Design Reviews	91	24
3 Subcontractor Control	70	76
4 Failure Reporting And Corrective Action System (FRACAS)	51	65
5 Development testing: Test, Analyze, And Fix (TAAF) a.k.a.: Reliability Growth Testing	90	50
6 Failure Modes, Effects, and Criticality Analysis (FMECA)	90	20
7 Design of Experiment (DOE)	Not on Survey	Not on Survey
8 Parts Control	63	72
9 Environmental Stress Screening (ESS)	66	55
10 Reliability Qualification Testing (RQT)	89	32
11 Thermal Analysis	86	14

Table 1. Most Value-Added Reliability Activities

12.3 Reliability Program Goals and Objectives

The supplier's reliability program goals and objectives should take into account many organizational factors and give consideration to the following.

- Improve Product Reliability. A robust design¹⁸³ contributes to products which become

¹⁸¹ This type of testing is based on Highly Accelerated Life Testing (HALT), Highly Accelerated Stress Screening (HASS), Stress Life, etc. testing and may use additional engineering analysis such as Durability analysis.

¹⁸² Benchmarking Commercial Reliability Practices, Pg. 27 Par. 4.1.1 "... most value-added ..."

¹⁸³ AMERICAN SUPPLIER INSTITUTE @ <http://www.amsup.com/TAGUCHI/>

more tolerant to user's conditions, supplier processes, and other uncontrollable factors, and performs consistently under a wide range of conditions throughout its life cycle thereby significantly improving product reliability.

- Establish requirements with the customer. Reliability requirements are based on program or product objectives and, when possible, these reliability requirements should be tailored according to mutually agreeable customer performance requirements, product or component performance limitation and the supplier's reliability testing capabilities. Performance-based reliability requirements should, be evaluated for realism by both the customer and the supplier to make sure that the cost of the product will not be adversely affected by unnecessarily stringent reliability requirements.
- Ensure a clear understanding of customers goals, objectives, requirements, needs and wants. Reliability and failure terminology (what constitutes a failure and what failure rate is acceptable) must be communicated so each party understands their respective requirements and capabilities. Suppliers and customers measure product performance depending on their own objectives. Customers usually specify reliability in terms of measured reliability under specified operational and environmental conditions, such as failure rates, life expectancy, or life-cycle costs, which may or may not include factors within the supplier's control. Suppliers may use terms associated with profitability or quality to define reliability, such as parts per million defective (ppm), product returns, warranty costs or liability limits. Where the product has a reasonably high volume and will be in production for 3-5 years or more reliability may be stated in terms of future standards of performance or as continuous reliability improvements over a specified period of time.

12.4 Reliability Program Model

Figure 1. Reliability Program Model, illustrates the many experiments, modeling, tests, and reports that are provided during design, product development, production and after the product is made available to the customer. The first requirement is for a Reliability Program Plan and the final requirement (#2) is for failure reporting and corrective action. The results of these tests and experiments are made available to the designers in real-time and to the customer at the various design reviews.

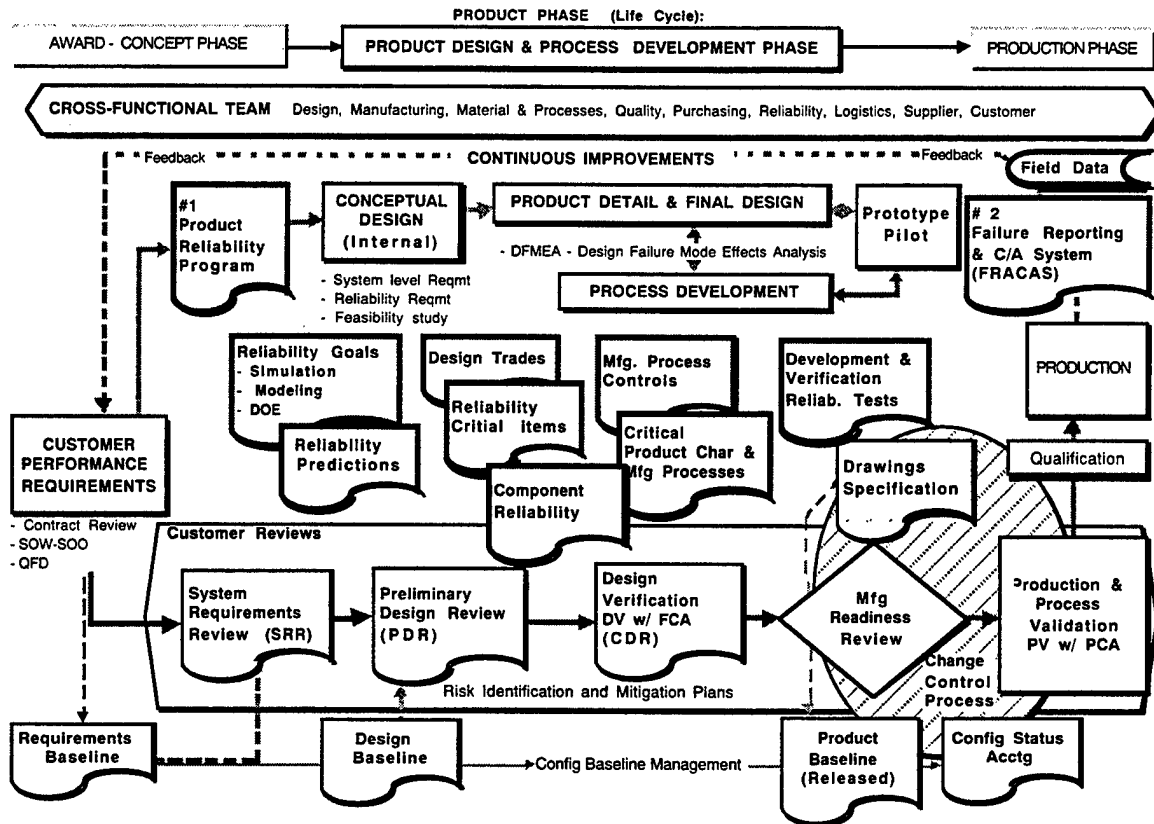


Figure 1. Reliability Program Model

12.5 Reliability Benefits

Increased product reliability customer benefits:

- Lower life-cycle costs by decreasing maintenance/support, reducing the number of spares, extending life-cycles and reducing redundancy requirements.
- Increased system safety by reducing risk to human life and equipment failures
- Increased product availability by reducing downtime
- Increased operational capabilities in extreme environments

Increased product reliability benefits the supplier by:

- lowered product costs by reducing returns,
- lowered warranty costs,
- increased market share and competitive advantage,
- reduced risk of liability.

12.6 Customer Reliability Requirements

The following is presented to provide the commercial supplier with the defense customer's point of view. Defense Customer Requirements drivers:

- Regulations and statutes. One primary reference is Department of Defense Regulation, March 15, 1996 Number 5000.2-R - Mandatory Procedures for Major Defense Acquisition Programs¹⁸⁴ (MDAPs) and Major Automated Information System (MAIS) Acquisition Programs. This regulation requires that "the Program Manager (PM) shall ensure that reliability, maintainability, and availability activities are established early in the acquisition cycle to assure meeting operational requirements and reduced life-cycle ownership cost. Reliability, maintainability, and availability requirements shall be based on operational requirements and life-cycle cost considerations; stated in quantifiable, operational terms; measurable during developmental and operational test and evaluation. The PM shall plan and execute reliability, maintainability, and availability design, manufacturing development and test activities such that equipment used to demonstrate system performance prior to production reflects the mature design."¹⁸⁵
- Performance requirements beyond normal commercial or industrial grade capabilities.
- Comparatively long product life cycles. See Section 11, Table 11-1 - Typical Product Life Cycles.

12.6.1 Customer Responsibility for Reliability

Customer reliability responsibilities.

- Providing supplier with customer requirements for:
 - reliability requirements or goals, such as mean-time-between-failure, or success probability,
 - environmental and operational conditions to which products will be exposed,
 - reliability tests which will be performed by customers upon receipt,
 - maintenance support concept and service/depot support, and
 - definition of a product "failure,"
- Reviewing supplier-furnished reliability information/analyses during the design phase
- Derating of product performance, where possible, during design parts selection
- Validating supplier's reliability claims by additional testing and feedback on field maintenance and other repairs

¹⁸⁴ A system shall be considered a major system if it is estimated by the USD(A&T) to require an eventual total expenditure for RDT&E of more than 75 million in FY 1980 constant dollars (approximately 140 million in FY 1996 constant dollars), or for procurement of more than 300 million in FY 1980 constant dollars (approximately 645 million in FY 1996 constant dollars) (10 USC 2302(5)).

¹⁸⁵ DoD 5000.2 Par. 4.3.6 Reference Only
Download from: http://www.safaq.hq.af.mil/acq_pol/dod5000/final/

12.7 Supplier Responsibility for Reliability

The supplier's role begins by actively participating in the customer's integrated product development team and providing the customer with information necessary to establish reasonable product reliability requirements.

The supplier should achieve the following objectives.

- 1) Communicate with the customer to establish a clear definition of the reliability requirements, goals, and needs
- 2) Determine that customer reliability requirements are achievable
- 3) Develop procedures and processes to satisfy the customer's needs
- 4) Develop methods to assure the customer that their needs have been met
- 5) Provide products that meet customer's requirements
- 6) Provide products that meet supplier's product dependability claims
- 7) Demonstrate supplier's understanding of reliability program practices through use of:
 - Defined procedures, process and "best" practices (analyses)
 - Screening to verify product reliability
 - Environmental or operational testing
 - Quality assurance testing
 - Continuous product or process improvement throughout the life cycle, and
 - Historical product reliability information.
- 8) Establish an on-going multi-functional design and manufacturing team with Reliability Engineering participation, and with various customers and key suppliers as necessary. As a member of this team, reliability engineers should participate in the following
 - Establishment of a Product Reliability Program (par. 12.8)
 - Product and process goals and objectives
 - Internal reliability procedures and standards and best practices
 - Analysis tools
 - On-going test and verification
 - Outputs (reports and feedback to design)
 - Design activities including:
 - Support and documentation of trade studies
 - System architecture definition and development
 - Design-of-Experiment testing
 - Parts selection and derating (graceful degradation)
 - Develop fault tolerant designs
 - Design reviews

- Establishment of on-going processes or procedures to reduce, eliminate or control product or system-level failures
 - Quality standards
 - Parts Control Program (Production Part Approval Process)
 - Manufacturing process control
 - Environmental Stress Screening (ESS)
 - Failure analysis, reporting, and corrective action

12.8 Product Reliability Program

Product reliability is a key requirement of the design agent during the conceptual design phase. However, the contract manufacturer or supplier's internal reliability program should address their understanding of the reliability requirements, techniques employed to design and develop a reliable product, and the planning, testing and documentation necessary for reliability verification. The reliability program should be described and provided to the customer in sufficient detail, as to clearly explain the reliability organization, inputs, routine testing conducted, outputs, and the effects on continuous product improvement as a result of these activities during the product life cycle. A successful reliability program has an interactive role with, and is an integral part of, life-cycle costs, product design, parts control, logistics, maintainability (testability), safety, testing, product returns and determination of warranties.

The supplier shall describe its internal reliability procedures, processes, standards, and tests which ensure that stated reliability requirements will be satisfied.

When the supplier's existing program reliability systems and procedures do not adequately address a customer's requirements, a Program Reliability Plan¹⁸⁶ is developed in sufficient detail to clearly describe the supplier's organization and intended approach for compliance with the customer's reliability requirements. This Plan may be combined with the overall Program Control Plan and typically requires customer approval prior to implementation or for any changes affecting the intent of the plan.

12.8.1 Reliability Program Organization

The supplier's reliability program establishes the procedures, processes and data necessary to establish and monitor product reliability goals which are based upon the following.

- Customer requirements
- Product objectives
- Industry benchmarks (other similar products)
- Competitive advantage in the marketplace

¹⁸⁶ IBP Best Practice identified in RAC and QS-9000

- Operational procedures and processes
 - Internal quality systems and standards
 - Design Engineering procedures
 - Supplier selection and control [JRM264]
 - Parts control including selection, approval, and substitution[JRM265]
 - Configuration management change controls

12.8.2 Reliability Program Analysis Tools

There are several analysis tools available for reliability prediction or determination. These tools usually include a mixture of the following techniques or tools.

- 1) Reliability Predictions. Estimates of probability of success (or failure). Reliability prediction tools selected must be appropriate for product requirements and operating environment and must be consistent with the product configuration.
- 2) Reliability Simulation. Used to reduce the time, resources, and risks associated with development of new technologies and to increase the quality and reliability of the product.
- 3) Reliability Models. Developed prior to the detail design being completed to facilitate early identification of changes affecting reliability in the final designs. Specific reliability objectives are used in development of the reliability model and prediction must be clearly defined such that when failures occur, the outcome can be compared to that used in the prediction model. Models are frequently used by commercial suppliers to establish product warranty and performance estimates. Reliability models should be updated with actual performance data at periodic intervals.
- 4) Failure Mode and Effects Analysis (FMEA). Analytical technique used during the product design phase (before failures occur) to insure that potential failure modes and their causes or their effects have been documented and addressed in the final product design. FMEAs can be placed into two distinct categories: design activities such as Design Failure Modes and Effects Analysis (DFMEA) and Failure Modes, Effects and Criticality Analysis (FMECA), or manufacturing activities such as Process Failure Modes and Effects Analysis (PFMEA).

Design Failure Modes and Effects Analysis. DFMEAs are conducted by a multi-functional team on both the product design and the process definition beginning at design concept finalization, prior to final design release and continuing throughout the product life cycle. FMEAs typically include:

- determination of failure mode, frequency, effects or risk assessment, and severity classification,
- failure detection and isolation methods, and
- compensating provisions such as re-configuration or addition of redundant functions and documentation of corrective action taken.

Failure Modes, Effects and Criticality Analysis. An early design review technique that examines potential failure modes to determine the effects of failures on equipment or system performance and establishes a failure “criticality” to the overall system or product. A FMECA extends the FMEA by including an assessment of all failure mode severity and probability of occurrence.

Note: Automotive industry design FMEA¹⁸⁷ refers to criticality as SEVERITY. Severity is ranked on a scale of 1 to 10, with 10 being highest “hazardous - without warning” and 1 being the lowest “no effect.”

Process Failure Modes and Effects Analysis (PFMEA). This analysis during the early process development phase examines manufacturing processes which may induce failures and determines the root cause and correction for such failure. Corrective action should, if possible, influence the design to permit the process to function within its normal capability range, or it may be necessary to establish a Special Characteristic designation to control the process more closely to avoid product variances.

- Design of Experiments (DOE). A designed experiment can improve a product design or the manufacturing processes used in development. These experiments are used to identify manufacturing process parameters or test techniques that affect the product’s performance, producibility and reliability. A DOE is one principal method for studying the effect and interaction of factors affecting the product reliability such as time, temperature, voltage or weather (humidity, salt-spray, moisture). Product application requirements analyzed by members of the cross-functional team¹⁸⁸ will determine physical and environmental factors to be tested. A matrix is established to record the results of varying the test parameters. Analysis of these results is then incorporated into the design or process controls.

- Statistical techniques applied to predictions.¹⁸⁹

Note: Statistical techniques are discussed in Production Processes Controls section.

- Benchmarking and trade studies. Conducted and compared with reliability predictions for similar proprietary products or with a competitor’s products.

12.8.3 Reliability Program Testing & Verification

Typical reliability verification by test or analysis¹⁹⁰ consists of the following

- Initial product demonstration or qualification test¹⁹¹

¹⁸⁷ Potential Failure Mode and Effects Analysis (FMEA), Chrysler Corp., Ford Motor Co. and General Motors Corp. 2/95, Pg. 13 Design FMEA - Severity

¹⁸⁸ See Section 1.0 Organizational and Technical Interfaces

¹⁸⁹ ISO 9004-1-1994 Par. 20.1 (c) dependability specification, longevity, and durability prediction

¹⁹⁰ Ford Motor Co. Q-1 Total Quality Excellence

¹⁹¹ Benchmarking Commercial Reliability Practices, RAC 1995 Pg. 22 Demonstration Testing (qualification) is not done, unless required by the customer (seldom) ...

- Reliability testing
 - Test, Analyze and Fix (TAAF)
 - Growth Testing
 - Formal Reliability Demonstration
- Accelerated testing
 - HAST - Highly Accelerated Stress Testing
 - HALT - Highly Accelerated Life Testing
- Screening tests
 - Thermal Shock
 - Electrical Tests
 - Temperature Cycling
 - Vibration
 - Humidity & Moisture

12.8.4 Reliability Program Outputs and Effects

- Design or Product Improvements. On-going efforts to improve product reliability by testing and data collection that should be employed include the following:
 - Identification of critical components¹⁹² and components subject to high failure rates to maintain product reliability
 - Reduction of high technology components and part types (standardization of components)
 - Parts approval and control initiatives
 - Implementation of parts stress derating (design margins) for electrical, thermal, mechanical characteristics
 - Use of higher quality components, if needed to improve reliability
 - Conduct component/part screening
 - Review of previous studies, service life estimates, and data for similar product
 - Perform product reliability testing
- Manufacturing or assembly requirements to improve reliability include:
 - Incorporation SPC or process control data tracking requirements
 - Integration reliability with design and manufacturing tools (CAD/CAM)
 - Establishment of inspection requirements
 - Specify special test conditions that will be necessary
 - Implement Production equipment calibration and maintenance program
- Performance feedback¹⁹³ from field data and internal test results are provided to the design, parts control, and reliability personnel in order to accomplish the following:

¹⁹² Reliability Toolkit: Pg. 123 Critical Item Reliability

¹⁹³ ISO 9004-1-1994 Par. 16.6 Market feedback ... throughout the life-cycle.

- Modify design rules to improve future product
- Modify reliability models to improve predictions
- Maintain historical product database for future parts selection
- Modify fault detection or isolation tools or methods in the assembly process
- Provide performance test results and information¹⁹⁴ to customers
- Failure and corrective action reporting includes the following:
 - Identification of corrective actions required to eliminate or reduce the probability of the failure mode occurring
 - Failure reporting of failure modes, root causes, risk assessment
 - Trend analysis of failure data

12.8.5 Reliability Program Product Reliability Report

In order to determine that a product is satisfactory for its intended application the customer may request that suppliers support their reliability claims by furnishing operational data, control charts¹⁹⁵ and test results that demonstrate the product is operationally effective and suitable for use. This is usually necessary during the proposal phase or during lower tier supplier parts selection process, but may also be requested at any time during the product life cycle. This applies to commercial-off-the-shelf (COTS) products as well as custom product.

12.9 Failure Reporting

Product failures can occur during the entire life cycle from design through production and distribution to the ultimate customer. Failure reporting to the customer requires a common understanding of what constitutes a failure. Typical failure definitions follow.

- Product does not meet a customer's performance requirement. Failure may be:
 - Catastrophic - sudden occurrence, complete product failure,
 - Chronic - repeats over a period of time or cycles, and
 - Latent - non-catastrophic, subsequent failure occurs due degraded condition.
- An event in which an item does not perform one or more of its required functions within the specified limits and under specified conditions¹⁹⁶.
- per Webster:
 - Omission or occurrence or performance
 - Failing to perform a duty or expected action
- Software Failure is the unacceptable departure of program operation from program requirements. See Attachment B - Software Reliability Overview.

¹⁹⁴ ISO 9004-1-1994 Par. 16.5 ... early warning system for reporting instances of product failure ... occurrence and modes of failure ...

¹⁹⁵ Production Part Approval Process, AIAG - Pg. 4 Submission levels

¹⁹⁶ MIL-STD-2155 Failure Reporting, Analysis and Corrective Action Systems

The supplier shall prepare and submit to the customer Product Failure Reports¹⁹⁷ for failures occurring during product development and/or the product warranty period as specified in the Statement of Objectives or Contract.

All failures occurring during product development (acceptance, burn-in, performance evaluation and qualifications testing) are analyzed for specific cause and effect and documented internally for design improvements¹⁹⁸ and production reviews. Failure reporting is available to the customer during the design reviews. This option usually applies to new products built exclusively for the customer.

When a failure occurs during the product warranty period or post-delivery activities¹⁹⁹ efforts to analyze and document product (field) failures should be reported. Suppliers have been reluctant to gather, analyze and provide this information to their key customers. However, where there is sufficient production volume, over an extended period, both parties can see the benefits to long-term agreements and other “partnering” or “teaming” arrangements. These long-term commitments require more information and more trust. This option usually applies to the supplier’s proprietary product that is sold with a warranty but also may apply to a customer product that is provided with a warranty.

Typical failure analysis activities.

- Fault detection/isolation
- Failure mode determined
- Root cause established
- Trend analysis performed
- Risk analysis performed
- Corrective action identified and implemented

Typical failure report should contain the following minimal information²⁰⁰

- Background: environment of failure, detection method, operational hours
- Item/process description
- Failure identification number (unique to each failure)
- Date of failure
- Component/part name/part number
- Component/part serial number

¹⁹⁷ MIL-STD-2155 Failure Reporting

¹⁹⁸ Reliability Toolkit: Commercial Practices Edition - Appendix B, Pg. 363 par. 2.9

¹⁹⁹ ISO 9004-1-1994 Par. 16 Post Production Activities, Par. 16.5 After Sales and Par. 16.6 Market feedback. RAC Blueprint RBPR 4 Pg. 13 “... failure reporting would continue after hardware is built”.

²⁰⁰ Reliability Toolkit: Commercial Practices Edition Pg. 310 Failure Analysis Report

- Date code
- Cause of failure
- Failure relevancy
- Investigative process to fault resolution, failure analysis (if conducted), corrective action (to prevent fault reoccurrence), failure history
- Analyses performance (failure modes and mechanisms)
- Graphic data
- Conclusion

Recommendation

- Corrective action and effectiveness
- References
- Distribution to all concerned parties

12.10 References

Internet access references Appendix C

12.11 Military Reliability & Maintainability Standardization Documents

The following table provides the status of US military Reliability and Maintainability (R&M) standardization documents. As a result of Defense Acquisition Reform, some R&M standards were retained while others were canceled outright, converted into handbooks, or replaced with non government standards (NGS). US military standardization documents can be obtained through the department of Defense Single Stock Point (DODSSP) either by phone, mail or fax. The address and Special Assistance Desk can be reached at:

DODSSP
Standardization Document Order Desk
700 Robbins Ave, Bldg. 4D
Philadelphia, PA 19111-5094
Tel. (215) 697-2667 Fax: (215) 697-2179

For Reference only. This table provides reliability standard's status as of first quarter 1997 and may not be all inclusive.

Document	Title	Status ²⁰¹
MIL-HDBK-344 (Aug. 1993)	Environmental Stress Screening (ESS) of Electronic Equipment (or one of the other system level stress screening documents such as the IES guide)	✓ active document
MIL-HDBK-189 (Feb. 1993)	Reliability Growth Management	✓ active document
MIL-HDBK-217 (Feb. 1995)	Reliability Prediction of Electronic Equipment	✓ active document
MIL-HDBK-251 (Jan 1978)	Reliability/Design Thermal Applications	✓ active document
MIL-HDBK-338 (Oct. 1988)	Electronic Reliability Design HDBK.	New HDBK scheduled for completion 3Q97
MIL-STD-470 (May 1989)	Maintainability Program for Systems and Equipment	5/95: Redesignate as MIL-HDBK-470 (short term) & consolidate w/ MIL-HDBK-471 ECD- 4/97
MIL-STD-471 (Jan 1975)	Maintainability Verification/ Demonstration/Evaluation	5/95: Redesignate as MIL-HDBK-471 (short term) & consolidate w/ MIL-HDBK-470 above

²⁰¹ NGS = Non Government Standard

MIL-STD-690 (Mar 1993)	Failure Rate Sampling Plans and Procedures	√ active document
MIL-STD-721 (Jun 1981)	Definition of Terms for Reliability and Maintainability	12/95: Canceled
MIL-STD-756 (Aug. 1982)	Reliability Modeling & Prediction	2/96: Canceled
MIL-STD-781 (Oct. 1986)	Reliability Test Method Plan, & Environments for Engineering, Development, Qualification, & Prod.	Combined into MIL-HDBK-781A
MIL-STD-785 (Aug. 1988)	Reliability Program for Systems and Equipment Development and Production	Canceled when NGS available. Both IEEE and SAE are developing Reliability Program Standards
MIL-STD-790 (Aug. 1995)	Standard Practice for Established Reliability and High Reliability Qualified Products List (QPL) Systems for Electrical, Electronic and Fiber Optic Parts Specifications	√ active document
MIL-STD-883 (Mar 1995)	Test Methods, and Procedures for Microelectronics	Retain as Test Method Std Ref. ANSI/J-STD-003
MIL-STD-1543 MIL-STD-1543A (Oct. 1988)	Reliability Program Requirements for Space and Missile Systems.	5/95: Cancel when NGS available ECD: 12/97 Ref. MIL-STD-785
MIL-STD-1629 (Nov 1984)	Procedures for Performing a Failure Mode, Effects, and Criticality Analysis. (FMECA)	Canceled W/O replacement 5/95 SAE FMECA STD ECD: 1Q98
MIL-STD-1629A	Procedures for Performing a Failure Mode, Effects, and Criticality Analysis. (FMECA)	Canceled W/O replacement 5/95 SAE FMECA Std 4Q96
MIL-STD-1635 (Oct. 1986)	Reliability Growth Testing	Canceled
MIL-STD-1843 (Aug. 1995)	Reliability-Centered Maintenance	8/95: Cancel when NGS available. SAE G-11 new HDBK See MIL-STD-2173
MIL-STD-2068 (Jan 1987)	Reliability Development Test (RDT)	Canceled
MIL-STD-2155 (Dec 1995)	Failure Reporting, Analysis and Corrective Action Systems (FRACAS)	Canceled 12/11/95 superseded by MIL-HDBK-2155
MIL-STD-2164 (Jan 1996)	Environmental Stress Screening (ESS) Process	Redesignate as MIL-HDBK-2164A 6/96
MIL-STD-2165 (Feb. 1993)	Testability Program, for Systems and Equipments	7/96: MIL-HDBK-2165 issued

MIL-STD-2173 (Dec 1989)	Reliability-Centered Maintenance	SAE G-11 new HDBK similar to the Air Transport Association's Maintenance Steering Group (MSG-3) RCM standard used by commercial airline industry
----------------------------	----------------------------------	---

Table 2. Military R&M Standardization Document Status

12.12 Software Reliability Overview

Analytical models and metrics exist for estimating software reliability and measuring characteristics of software. Software Reliability makes sense, especially since:

- Systems are becoming software intensive;
- Many software-intensive systems are safety critical;
- Customers are requiring more reliable software; and
- The cost of developing software is increasing.

The following is a brief overview of Software Reliability.

Software reliability is a relatively new concept. Software does fail, but not in a manner similar to hardware - since software failures are not caused by aging; fatigue; etc. Software failures are defined as the manifestation of a human error. With human error being: oversight, omission or commission made in interpreting requirements, implementing design or code, or making modifications and/or enhancements.

The relative cost to fix software bugs increases by a factor of 10, for each of the following phases: design; code; test and field.

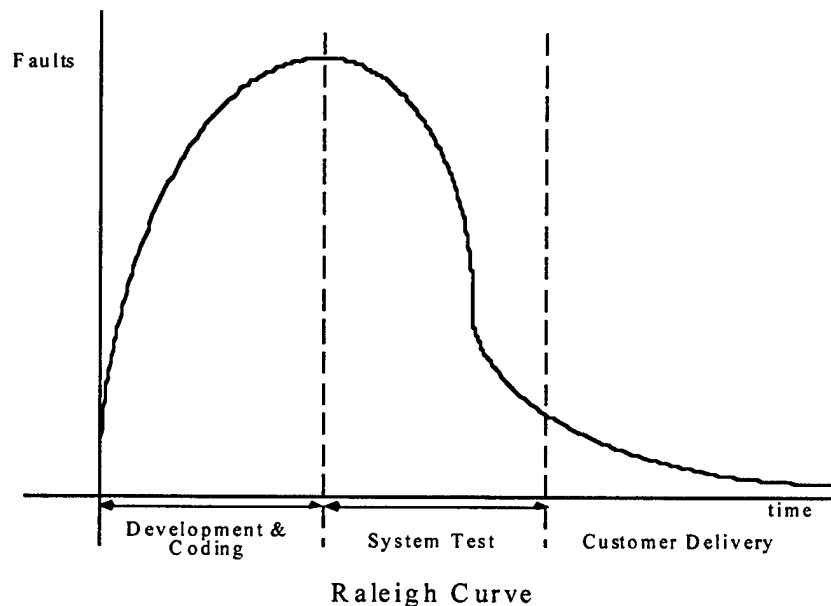
The following factors have been found to impact software reliability:

- 1) Application Type
- 2) Methodologies
- 3) Product Characteristics
- 4) Testing/Verification
- 5) Schedule
- 6) Maintenance
- 7) Operational Profile
- 8) Organization/Management

It is noteworthy to mention that data collected by QSM²⁰², and substantiated with data collected by SoftRel, shows that faults detected over the course of the software life cycle typically represent a Raleigh Curve (below). This information is very useful in providing confidence that the software has not been over/under tested, and is in fact ready for delivery to the customer.

²⁰² Quantitative Software Management (QSM) Tel: 800-424-6755 ? FAX: 703-749-3795

Since the early 1980's, several Software Reliability Models have been developed to predict or estimate Software Reliability. The Prediction Models are used to predict reliability of software at some future time. Predictions can be made prior to development or test, as early as concept phase. These tools are usually based on historical data. The Estimating models estimate reliability of the software at some present or future time based on data collected from current development and/or test. Estimators are normally used later in life cycle then predictors.



12.12.1 Software Reliability Prediction and Assessment Methods

- Rome Laboratory TR-92-15 "Reliability Techniques for Combined Hardware and Software Systems". This technical report outlines techniques for reliability prediction, allocation, growth and demonstration testing of systems that contain both hardware and software. The techniques are compatible with those hardware reliability concepts, standards and procedures in use at the time of the document's writing. Rome lab is present updating the techniques based on an industry and government review and comments process. A revision will soon be available as RL-TR-97-TBD, "System and Software Reliability Assurance".
- Rome Laboratory TR-92-52 "Software Reliability Measurement and Testing" Similar to the Hardware Approach documented in MIL-HDBK-217. Predicts Fault Density (Faults/SLOC); Can be applied during concept; design or coding phases. Presently, this model is the most commonly used in industry. It is a good tool to use for design trade-off. For early phases of a program, the following fault densities (faults/1,000 lines of code) can be used:

Type of Software	Faults
Airborne	0.13
Strategic	0.009
Tactical	0.008
Process Control	0.002
Production Control	0.009
Developmental	0.014
Average	0.010

Musa Execution Failure Rate Prediction. Predicts the failure rate of a system at the point in which system testing begins.

- **Putnam Model.** Assumes that faults detected per time forms a Raleigh Curve. Benefits of this model: a) Expected number of faults can be predicted for various points in the life cycle; and b) Can make fault estimates from fault data prior to test.
- **Industry Data.** Data has been collected by various industry individuals & organizations correlating fault density to software reliability factors. One of these organizations is Software Productivity Research, Inc. which has collected data showing a correlation between the Software Engineering Institute Capability Maturity Model level and fault density in terms of Function Points. They also found a correlation between fault density in terms of function points and industry type. Benefits of this approach are that it is simple and based on factors that have been shown to correlate with reliability.
- **Internally Collected Historical Data.** Some companies predict Software Reliability by collecting historical data on their own software projects, i.e.: Fielded failure data per project; Software reliability factors; and Regression Analyses.

12.12.2 Software Reliability Estimation Models

- **Various Exponential Models,** including some of the more popular: Shooman Model Lloyd-Lipow Model; Musa's Basic Model; and the Goel-Okumoto Model. These models are simple to use. In general, these models assume that: a) Failure rate directly related to number of faults in program; b) All faults are equal in severity and probability of detection; c) All faults are independent of each other; d) Software is in an operational state; and e) Faults are removed immediately.
- **Historical Data Collection.** This model is a hybrid between the Software Reliability Predictor and Estimator Tools. Rome Laboratory Technical Report TR-92-15 contains a fault count model which is based on collected historical data and regression analyses. Since this model was based on data collected by only one company, in only one industry/application type it was presented for information, and was *not* recommend for use by the instructor.
- **Weibull Model.** The Weibull model is one of the earliest models applied to software. It can be used when there is an increasing, decreasing or constant failure rate for software. This model is a general form of the exponential and Raleigh models.

12.12.3 Test Coverage Models

Assumes that software reliability is a function of the amount of product that has been successfully verified or tested. These models include:

- IEEE Test Coverage Model. This model assumes that reliability is a function of the functions that are tested (black box testing) and the product that is tested (white box testing). It assumes that both types of testing have to be completed for the test coverage to be complete.
- Leone's Test Coverage Model. This model is similar to the IEEE model, except it assumes that it is possible to have either white or black box testing and still have a high degree of reliability.
- Test Success Model. This model assumes that reliability is a function of the total successful test cases over the total test cases executed.
- Tagging Models. These models are based on seeding theory. The basic concept is to:
 - Inject known software failures into the code
 - Don't tell the code testers where the injected failures are
 - Have the code testers try to find the injected failures.
 - Since these models require configuration changes to the code, they are absolutely *not* recommend for use.
- Dual Test Group Model. This is a tagging model which simulates the seeding of faults, and assumes: a) Two independent test groups are testing same software at same time; b) Groups do not share information on faults detected in testing; c) Groups create their own test plans, but test the same functionality of the software; and d) Groups are equal in experience and capabilities. Since two completely independent test groups are required, implementation of this model is very expensive and often not practical.
- Bayesian Models. These models differ from the other models because a subjective approach is taken to modeling reliability. The other models assume that reliability & failure rate is a function of a fault being detected. Bayesian models, on the other hand, assume that a program which has had fault free operation is more likely to be reliable. These models are not as mainstream as classical models.

Prior to selecting one of the above Predictor or Estimating models, it is important to consider the data requirements and limitations of each model. It is also important to select the right model for the right phase of the program.

12.12.4 Additional Tools

- Software Fault Tree, this tool is used to: a) Determine areas in the product which could cause a potential failure; and b) Determine risk and severity of any such sources of potential failure.

- Software FMEAs. FMEAs are used on software to: a) Determine contingent aspects of design; b) Reveal potential critical failure modes; c) Reveal what software units will cause them; d) Determine the unit's effect on the system and subsystem, in the event of the failure mode existing; e) Determine the probability and criticality of the failure modes; and f) Prompt defensive action to mitigate critical failure modes from design.

12.12.5 System Reliability & Software Redundancy Models

- Series Configuration Model. A series configuration is when a group of components fails if and when any one of its components fails. *This Model is used when* software Computer Software Configured Items (CSCI) are in series with other CSCIs and with Hardware Configured Items (HWCI).
- Parallel Concurrent Model. When there are a group of components which all operate simultaneously and all must fail for the system to fail. There is a parallel concurrent configuration; there is no voting mechanism on results output by the components, but rather each component does some job. *This model is used when* all software CSCIs must continuously operate concurrently.
- Semi-Markov Model. This technique can be used to model a system where components execute one after another with known probabilities. This technique assumes that the future is completely determined by a present state and that the time in each state before a transition is random. *This model is used when* a system reliability based on transitions between hardware/software or software/software is desired.
- Mission Oriented Model. This mission oriented model can be used when the exact start and stop time of each CSCI is not known, but the failure rate and total active time for each operational mode are known. The average failure rate can then be calculated. *This model is used when* transitions or time spent in each transition is unknown. When software operates in phases and/or modes based on a mission profile, and the failure rate of CSCIs is known.
- Operational Profile Oriented Model. The operational profile oriented model can be used when the exact start and stop time of each CSCI is not known, but the failure rate, total active time for each operational mode, and the operational profile are known. *This model is used when* transitions or time spent in each transition is unknown. When software operates in phases and/or modes, the operational profile is known, and the failure rate and size of CSCIs is known.

Checklists are also available to assist in software anomaly management.

OTHER SOFTWARE REFERENCES

“Reliability Techniques For Combined Hardware And Software Systems” Rome Laboratory, TR-92-15

“Software Reliability Measurement & Testing”
Rome Laboratory, TR-92-52

“Recommended Practice for SOFTWARE Reliability”
American Institute of Aeronautics & Astronautics
ANSI/AIAA R-013-1992, Washington, DC 1992

“CECOM Executive Management Software Metrics”
Center for Software Engineering
J. McGhan, Peter B. Dyson, 1991
AMSEL-RD-SE-ST-SE
Ft. Monmouth, NJ

“Software Reliability Handbook”
Centre for SOFTWARE Reliability
Elsevier Applied Science

Appendix A - Requirements Summary

1. MANAGEMENT

- 1) (Par. 1.1) The supplier shall describe its organizational and technical interfaces, responsibility, and authority with respect to design, parts control, configuration and data management, quality planning, source selection, development and production activities²⁰³.
- 2) (Par. 1.2) The supplier shall return the Operational Requirements Matrix²⁰⁴ showing the relationship of the customer's business practice requirements to the supplier's existing quality system procedures, instructions or control plans.
- 3) (Par. 1.3) The supplier shall establish, document and maintain a Program Control Plan²⁰⁵ as mutually agreed and shall submit for customer review and acceptance.
- 4) (Par. 1.3.1) The supplier shall establish, document and maintain as necessary, a schedule of key project events²⁰⁶ and provide for customer review as soon as possible after contract award.
- 5) (Par. 1.3.2) The supplier and customer shall mutually establish a Customer Participation Plan for design reviews and verification, and product validation or inspections prior to production release.

2. DESIGN CONTROL

- 1) (Par. 2.3) Supplier shall describe its internal design control procedures²⁰⁷, processes, standards, reviews and product validations which ensure that stated performance and reliability requirements will be satisfied.
- 2) (Par. 2.8.2) The design agent shall plan and conduct a formal, documented System Requirements Review²⁰⁸ including customer participation and appropriate personnel representing the functions being reviewed and any other specialized functional personnel as required, and as indicated in the Program Control Plans.
- 3) (Par. 2.7.3) The design agent shall plan and conduct a formal, documented Preliminary Design Review including customer participation and appropriate personnel representing the functions being reviewed and any other specialized functional personnel as required, and indicated in the Program Control Plans.
- 4) (Par. 2.7.4) The design agent shall plan and conduct a formal, documented Design Verification Review including customer participation and appropriate personnel representing the functions being reviewed and any other specialized functional personnel as required, and indicated in the Program Control Plans.

²⁰³ QS-9000 Quality System Requirements par. 4.1.2 Organizational interfaces,
QS-9000 Quality System Requirements par. 4.2.3 Use of Cross-functional teams
ISO Q9001-1994 par. 4.1.2.1, 4.4.3

²⁰⁴ ISO Q9001-1994 par. 4.2.3 Note 8: ... in the form of a reference ...

²⁰⁵ ISO Q9001-1994 par. 4.2.3 Quality Planning

²⁰⁶ ISO Q9004-1 par. 8.2.3 Time-phased Design activities

²⁰⁷ ISO Q9001-1994 par. 4.4.1 documented procedures...

²⁰⁸ ISO Q9004-1-1994 par. 8.2 Design Planning & Objectives

3. PARTS CONTROL PROGRAM

- 1) (Par. 3.1) Supplier shall describe its internal parts control²⁰⁹ procedures and processes for selection, qualification, standardization, approval and data collection for parts to be used in the product design and manufacture.
- 2) (Par. 3.4) The supplier shall establish, document and maintain as necessary a process for advanced customer notification²¹⁰ of proprietary product phaseout or of changes to any product that may affect the customer's intended application's form, fit, or function.

4. CONFIGURATION MANAGEMENT

- 1) (Par. 4.1) The supplier shall describe their internal Configuration Management²¹¹ procedures, processes, and standards to control changes and provide a positive method of ensuring current released documents are available in a timely manner, at appropriate locations, during the product life cycle.
- 2) (Par. 4.2) The supplier shall establish formal Subcontractor Configuration Control²¹² procedures to establish the extent of their control over subcontractors, as appropriate to the product being acquired.
- 3) (Par. 4.3) The supplier shall establish a formal Configuration/Change Control Board²¹³ (CCB) or equivalent process for the management, review and approval of all changes, internally or externally generated, affecting a baseline, i.e. drawings, specifications, and variances.
- 4) (Par. 4.4) The supplier shall provide for effective management of product interfaces.²¹⁴
- 5) (Par. 4.7) The Part Identification Number²¹⁵ shall be changed whenever a non-interchangeable functional or physical condition is created or when new or revised testing, maintenance, repair, training, operating procedures or manuals, equipment or software is required.
- 6) (Par. 4.8) The supplier shall establish by mutual agreement with the customer, Configuration Baselines (B/L)²¹⁶ according to the program phase: (a) Requirements B/L, (b) Design Release B/L, or (c) Production B/L.

209 ISO Q9001-1994 par. 4.4.2 Design & Development planning
BOEING CAS: D900-10193-1 Pg. 15 par. 3.1 Parts Control Plan

210 QS-9000 Quality System Requirements, Section II pg. 52, Production Part Approval Process

211 ISO 10007:1995-04-15 Guideline for Configuration Management par. 5.3, 7.4, 7.7
ISO Q9001-1994 par. 4.5.1 Document and Data Control

212 EIA 649-95 par. 5.1.6 Supplier Configuration Management "... when there is a rational need ... as appropriate to the product being acquired."
ISO Q9001-1994 par. 4.6.2 b) "... control exercised ... over subcontractors."

213 ISO 10007:1995-04-15 par. 3.4, 7.3 Configuration Board
ISO 9001: par. 4.5.3 Document and Data Changes

²¹⁴ ISO 10007:1995-04-15 par. 7.2.1, 7.4.2 ... evaluation of changes ...

²¹⁵ ISO 10007:1995-04-15 par. 5.2.3 & 7.2.3
EIA IS-649-95 par. 5.2.3.d Product Identification

216 ISO 10007:1995-04-15 par. 3.3, 5.2.4, 7.2.4, Annex C
EIA IS-649-95 par. 5.2.5 Baselines

- 7) (Par. 4.9) All changes or variances to officially released documentation (design documents, specifications, procedures, drawings) shall require review and approval, prior to making document changes²¹⁷, by the original approving functions or document owner, and authorization by a formal engineering change document.
- 8) (Par. 4.9.1) All Major (Class I) changes, including those proposed by supplier/subcontractors, shall require formal communication with the customer or drawing owner using the supplier's own form and written approval by a designated approval authority²¹⁸.
- 9) (Par. 4.10) When a known departure from requirements is incorporated, the supplier shall document a Request for Variance and obtain appropriate authorization.²¹⁹
- 10) (Par. 4.11) The supplier shall maintain a Configuration Status Record²²⁰ with contents mutually defined as indicated in the contract and Program Control Plan.
- 11) (Par. 4.12) The supplier shall have an effective Disaster Recovery Plan²²¹ and process in place to enable reproduction of both historical and current documents and data including supplier-generated documents and data for the product design, production & test in the event of potential destruction by fire, flood, theft or other forms of loss.
- 12) (Par. 4.13) A serial/lot number and/or supplier identification number shall be assigned to each Model number or Configuration Item (CI) unit for the purposes of control, traceability²²² and customer acceptance.
- 13) (Par. 4.14) The supplier shall provide an As-Built Configuration Report²²³ with contents as defined in the contract and Program Control Plan, to verify that all Major (Class I) changes were incorporated into the product and to indicate approved variances.
- 14) (Par. 4.15.1) At the completion of product development, the design agent shall conduct a formal design verification Functional Configuration Audit²²⁴, verifying the customer requirements against the Design Released Baseline. A design Certificate of Compliance shall be submitted by the design agent, which affirms that the design meets customer's Form, Fit, Function & Interface requirements.

217 ISO Q9001-1994 par. 4.5.3 Document and Data Changes

ISO 10007:1995-04-15 par. 7.4

218 EIA IS-649-95 Pg. 26, 5.3 (b) Change Management; 5.3.1.2 (a) Major

ISO 10007:1995-04-15 par. 7.4

219 ISO 10007:1995-04-15 par. 7.3, 7.5.2

EIA IS-649-95 Pg. 34, par. 5.3.4

220 ISO 10007:1995-04-15 par. 7.5.3 CSA Reporting

EIA IS-649-95 Pg. 34, par. 5.4

221 ISO 10007:1995-04-15 par. 5.3 Configuration Control - disaster recovery

222 ISO 9001 Quality Systems Model par. 4.8 Product Identification and Traceability

EIA IS-649-95 par. 5.2.3.1 Identifying individual units

223 ISO 10007:1995-04-15 par. 7.6 Configuration audit procedure "as built/produced"

EIA IS-649-95 Pg. 38, par. 5.5 Figure 12

MIL-STD-973 App. H Task 501 pg. 199

224 ISO 10007:1995-04-15 par. 7.6 Configuration Audit Procedures

ISO 9004 par. 8.5.3 Design Verification

- 15) (Par. 4.15.2) The supplier's cross-functional team shall conduct a physical product examination²²⁵ of the first production unit's "as built" configuration against its technical documentation prior to production of contract quantities. The extent of customer involvement is documented in the Program Control Plan. A product Certificate of Conformance is required with First Article Inspections, Production Readiness Reviews, or Initial Production Validations, as applicable.

5. QUALITY SYSTEM

- 1) (Par. 5.4) The supplier shall describe their facility-wide Quality System meeting the intent of ISO Q9001-1994²²⁶ or ISO Q9002-1994 as indicated in the contract and Statement of Objectives.
- 2) (Par. 5.5.2) The supplier shall provide for customer witnessing of Initial Production Validation lot. These validation points and methods shall be documented in the quality planning documents.
- 3) (Par. 5.5.3) The supplier shall provide for customer witnessing of in-process inspections²²⁷ for product key characteristics that are not controlled by SPC. Appropriate sampling may be used and defined in the Program Control Plan.
- 4) (Par. 5.5.4) The supplier shall provide a report of Final Inspection results and a Certification²²⁸ of Final Inspection for each unique serial number or lot as indicated in the contract and Program Control Plan.
- 5) (Par. 5.5.5) The supplier shall provide for customer witnessing of final product inspection²²⁹ and/or acceptance testing and a Certification²³⁰ of Final Acceptance for each unique serial number or lot as indicated in the contract and Program Control Plan.
- 6) (Par. 5.6) The supplier shall allow for final determination by the customer,²³¹ or their representative, for "use as is" and "repair" dispositions and for any major nonconformances.
- 7) (Par. 5.7.1) Supplier shall provide for Quality Records Retention and customer access, for the period of time²³² as stated in internal company procedures or as mutually agreed and defined in the contract or Statement of Objectives.
- 8) (Par. 5.8) The supplier shall establish, document and maintain a Continuous Improvement Program²³³ that is applicable throughout the organization and includes procedures, instructions and reporting of product or process variability reduction efforts together with monitoring of Key Characteristics.
- 9) (Par. 5.9) The supplier shall demonstrate their Cost-of-Quality²³⁴ measurement system including internal management reporting and trend analysis.

²²⁵ ISO 10007:1995-04-15 par. 7.6

²²⁶ ISO Q9001-1994 Par. 4.2.2 Quality System Procedures

²²⁷ ISO Q9001-1994 Par. 4.10.3 In-process inspections

²²⁸ ISO Q9001-1994 Par. 4.10.4 Final Acceptance inspection

²²⁹ ISO Q9001-1994 Par. 4.10.4 Final Acceptance inspection

²³⁰ ISO Q9001-1994 Par. 4.10.4 Final Acceptance inspection

²³¹ ISO Q9001-1994 Par. 4.13.2 "... reported for concession to the customer ..."

²³² ISO Q9001-1994 Par. 4.16 "Retention times ... shall be established and recorded ... for a agreed period.

²³³ ISO Q9004-1 Par. 5.6 Quality Improvement

²³⁴ ISO Q9004-1-1994 Par. 6.2.2 a) Quality-costing approach

6. SOURCE SELECTION

- 1) (Par. 6.1) The supplier shall describe their internal process for management of Source Selection Policies and/or Procedures²³⁵ which ensure that stated performance and reliability requirements will be satisfied.
- 2) (Par. 6.4) The supplier shall describe and demonstrate how past performance information and periodic evaluations are used in future source selection decisions and the management of the existing supplier base.

7. PROCUREMENT DATA

- 1) (Par. 7.1) The supplier shall establish and maintain Procurement Procedures²³⁶ to ensure internal review and approval of procurement documents, and the proper communication of contractual requirements, product requirements, and technical data to sub-tier suppliers.
- 2) (Par. 7.4) Supplier shall provide evidence of periodic, independent, internal Procurement System reviews²³⁷ to ensure compliance with company policies and procedures.

8. CUSTOMER-OWNED PROPERTY MANAGEMENT

- 1) (Par. 8.1) The supplier shall describe their internal process for management of customer-owned property²³⁸ which ensures that stated performance and reliability requirements will be satisfied.
- 2) (Par. 8.3) The supplier shall:
 - a) verify²³⁹ the identify and condition of customer property upon receipt.
 - b) provide proper care, maintenance, and storage of customer property.
 - c) ensure that customer property is not physically commingled with other product, either customer-owned or from other sources, and that the customer property is not used in other contracts.²⁴⁰
 - d) maintain a recording and reporting system to track customer property to include receipt at the supplier, inventory transactions (issues & receipts), scrap, loss, damage, location and returns
 - e) track and report customer property in the possession of subcontractor.
- 3) (Par 8.4) The supplier shall dispose²⁴¹ of customer-owned property according to customer written instructions at conclusion of the contract or when no longer needed, whichever is sooner.

²³⁵ ISO 9001-1994 par. 4.6 Purchasing

²³⁶ Ref. ISO 9001-1994 Par. 4.0, 4.1.1, 4.2.2, 4.2.3, 4.6.2, 4.6.3

²³⁷ ISO 9001-1994 Par. 4.1.3 Management review

²³⁸ ISO 9001-1994 par. 4.7 Control of Customer-Supplied Product (procedures)

²³⁹ ISO 9001-1994 par. 4.7 Control of Customer-Supplied Product (verification)

²⁴⁰ ISO 9001-1994 Par. 4.15.3 Handling, Storage, Packaging, Preservation & Delivery,

ISO 9001-1994 Par. 4.7 Control of Customer Supplier Product

²⁴¹ FAR 52.245-2 Reqmt (i) Final Accounting and disposition...

FAR 45.6 Reporting, Redistribution, and Disposal of Contractory Inventory

9. HANDLING, STORAGE, PACKAGING & DELIVERY

- 1) (Par. 9.1) The supplier shall describe its internal Handling & Packaging procedures²⁴², processes, standards, and tests to ensure that products are handled, stored, preserved, packaged, labeled, documented and shipped in a sufficient manner to prevent damage, deterioration, degradation, loss, or substitution of the product and to otherwise protect the Form, Fit or Function of the product.
- 2) (Par. 9.2) The supplier shall package the product for protection after final inspection and test, during delivery of the product to the customer,²⁴³ and during storage at the customer's facility in conformance to federal and state requirements and to the customer requirements as stated in the contract.
- 3) (Par. 9.3) Bar coding of the external packaging is required. Bar code symbology shall be as specified in the statement of objectives or product performance specifications²⁴⁴.
- 4) (Par. 9.4) As applicable, sensitive electronic devices shall be protected from electro-static, electro-magnetic, magnetic and radioactive forces by properly safeguarded work stations and properly outfitted personnel during fabrication, assembly, test processing or packaging, and by the use of electrostatic discharge protective packaging materials during storage and shipment.²⁴⁵

10. MANUFACTURING PROCESS & CONTROLS

- 1) (Par. 10.1.1) The supplier shall describe its internal manufacturing procedures, processes, standards, and tests which ensure that stated performance and reliability requirements will be satisfied.
- 2) (Par. 10.1.2) The supplier shall establish process review points, notify the customer, and obtain approval²⁴⁶ as required prior to any process changes that affect the product's form, fit, function or interface requirements.
- 3) (Par. 10.1.5) All processes affecting a Critical or Key Characteristic shall require a Cpk =1.33. When these processes are less than 1.33, the supplier shall submit a plan and schedule for attaining a Cpk =1.33²⁴⁷. The supplier may alternately choose to perform 100% in-process product inspections.
- 4) (Par. 10.2.1) The supplier shall provide Process Controls reports on an exception basis, as specified in the contract or Statement of Objectives.
- 5) (Par. 10.3) The supplier shall provide operational and process capability demonstrations to the customer as specified in the contract or Statement of Objectives.
- 6) (Par. 10.4.1) Variability Reduction Instructions shall be included in manufacturing instructions or other process control documents which emphasize the control of Key

²⁴² ISO 9001-1994 Par. 4.15 Handling, Storage, Packaging, Preservation, and Delivery

²⁴³ ISO 9001-1994 Par. 4.15.4 "...conformance to specified requirements."

²⁴⁴ ISO 9001-1994 Par. 4.15.4 Packaging

MIL-STD-2073 DoD Standard Practice for Military Packaging Par. 4.1.1;

MIL-STD-130 Identification Marking of US Military Property (Standard Practice)

²⁴⁵ ISO 9001-1994 Par. 4.15.5 Preservation

²⁴⁶ ISO 9001-1994 Par. 4.9 (e) ... approval of process and equipment, as appropriate...

²⁴⁷ QS-9000 Ford Specific Requirement, page 68

Characteristics.

11. PRODUCT SUPPORT (LOGISTICS) REQUIREMENTS

- 1) (Par. 11.2) The supplier shall establish, document and submit for customer approval, a Product Support Plan²⁴⁸ to ensure continuity of supply during the product life-cycle or as stated in the contract.
- 2) (Par. 11.43e) supplier shall prepare and submit to the customer, Product Failure Reports²⁴⁹ for failures occurring during product development and/or the product warranty period as specified in the Statement of Objectives or Contract.

12. RELIABILITY REQUIREMENTS

- 1) (Par. 12.8) The supplier shall describe its internal reliability procedures, processes, standards, and tests which ensure that stated reliability requirements will be satisfied.
- 2) (Par. 12.9) The supplier shall prepare and submit to the customer Product Failure Reports²⁵⁰ for failures occurring during product development and/or the product warranty period as specified in the Statement of Objectives or Contract.

²⁴⁸ ISO 9004-1-1994 Par. 16.4.3, 16.4.4 Postproduction Activities

²⁴⁹ MIL-STD-2155 Failure Reporting

²⁵⁰ MIL-STD-2155 Failure Reporting

Appendix B - Key Characteristics

1. Guidelines for Control of Key Characteristics

The purpose of this Appendix is to provide a means of identifying, tracking, and controlling product Key Characteristics.

- Definition: Key Characteristics identify measurable product characteristics or process parameters that influence the form, fit, function, interface²⁵¹ or reliability of the final product and require special attention or controls during design, processing, manufacturing, assembly or testing.

Figure 5. Key characteristics evolution and control illustrates the evolution of key characteristics that are identified by the customer, usually on the drawings, as performance or interface requirements and subsequently by the supplier as processes that can may affect those customer requirements.

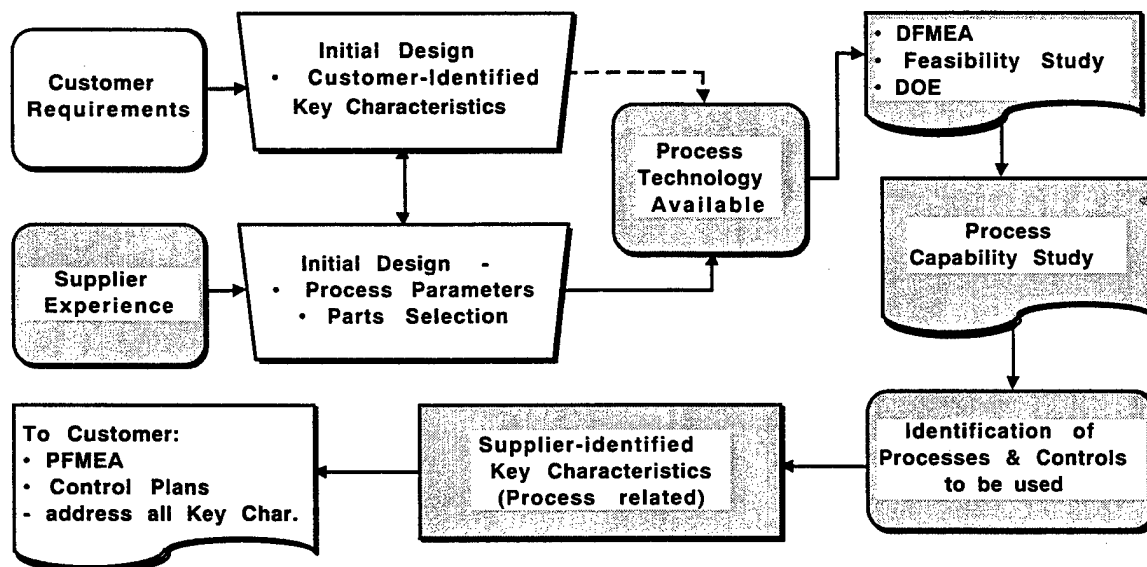


Figure 5. Key characteristics evolution and control

Key Characteristics are developed through a process of evaluating the design and manufacturing processes and by gaining an understanding of the needs and requirements of the Customer, referred to as "Voice of the Customer"²⁵². While the customer's expectation is that all

²⁵¹ Interface characteristics can be described as the product features where variation significantly affects Form, Fit, orientation, location with tooling and mating parts, or performance in Functional testing:

• product to higher level • product to tooling • product to test equipment. (C-17 Definition 4/96)

²⁵² Quality Functional Deployment, American Supplier Institute

requirements be met (i.e.: reliability, maintainability, function, appearance, etc.), Key characteristics will have a direct effect on the products ability to perform. Although this section is not identified as a requirement, it is referenced in several sections and describes one method for compliance with the requirement for control of Key characteristics.

Key characteristics are not limited to specified design requirements but may also apply to the “Voice of the Customer” objectives. The design-related characteristics are typically designated as “Critical”, “Safety”, “CSI” (Critical Safety Item), “Significant”, or “INT” (Interface) depending on the customer and are controlled by dimensional tolerancing or performance output. Key Characteristics are typically referred to in manufacturing²⁵³ documentation and are controlled by statistical process controls.

Appropriate process controls must be established for all Key characteristics.

Note: Process controls are discussed in Production Process Controls - Section 10.

Critical Characteristic

Properties of the product or process which, if allowed to (go out of limit) exceed the specified tolerances and will result in a failure of the product to perform safely resulting in loss of life or failure of the end product’s mission performance²⁵⁴.

Significant Characteristic

Properties of the product or process which, if allowed to exceed their limits, will result in failure of the item to function or cause it to function erratically, intermittently, or generally fails to meet the customers performance expectations over the design life and which prevents product integration.

Customer-designated Key characteristic

Customer-designated Key characteristics are established when critical form, fit, functional or interface design requirements dictate that special design controls or attention be considered.

These characteristics are generally related to higher level system performance and integration requirements; which the supplier may not normally be aware of. They are provided by the customer as part of the product performance specification, technical data package (drawings) or Statement of Objectives.

²⁵³ Advanced Quality System for Boeing Suppliers© D1-9000 - Key Characteristics pg. 0-8

²⁵⁴ QS-9000 Appendix C: Special Characteristics - Safety/Compliance per GM; Critical Characteristic per Ford Motor Co.

Supplier-designated Key Characteristic

Supplier-designated Key characteristics are developed from reviews and comparison of the supplier's manufacturing process capabilities and technical experiences against the needs of the Customer, Performance Specification, and Statement of Objectives.

The process of identifying supplier-designated Key characteristics is generally accomplished by advanced Quality Planning teams (see Integrated Product Teams) using such techniques as: Quality Functional Deployment (QFD), Design Failure Mode Effects Analysis (DFMEA), and Design for Manufacturability, Assembly (DFM/A).

Critical Characteristic	▽	▼	<S>	CSI ²⁵⁵
Significant Characteristic		◆	S/C	INT
Process Characteristic	Defined in Control Plan HAZ			

Figure 2. Characteristic Symbols (Typical examples).

2. Identification of Key Characteristics

Key characteristics should be identified by a symbol on Process Control Plans generated by the supplier, and all item drawings provided by the customer. These identification symbols are defined and agreed upon by the customer or supplier. It is recommended that these symbols be included wherever a Key characteristic is addressed in the specifications, drawings, control plans, FMEAs, workorders, etc.

²⁵⁵ MIL-STD-100 Engineering Drawing Practices Pg. 500-6 "CSI" (Critical Safety Item), "INT" (Interface), or "HAZ" (Hazardous)

Appendix C - Internet References

1. Internet Access References

This alphabetical listing contains some of the Internet sites that were referenced during drafting of these Business Practices and others that we thought might be of interest.
Have fun!

AIRCRAFT INDUSTRIES ASSOCIATION OF AMERICA, INC. (AIA)

1250 Eye St., Washington, D.C. 20005-3922

(202) 371-8400

aia@millkem.com

American Institute of Aeronautics and Astronautics (AIAA)

<http://www.aiaa.org>

Listing of Associations: <http://www.aiaa.org/information/links/societies.html>

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

1430 Broadway, New York, NY 10018,

Tele: (212) 642-4900, FAX: (212) 302-1286.

<http://www.ansi.org>

AUTOMOTIVE INDUSTRY ACTION GROUP (AIAG)

800-358-3003

<http://www.aiag.org>

BEST MANUFACTURING PRACTICES (BMP)

<http://www.bmpcoe.org>

BOARD OF MANUFACTURING AND ENGINEERING DESIGN

<http://www2.nas.edu/bmaed/>

DEFENSE SUPPLY CENTER COLUMBUS (DSCC)

Home Page at: <http://www.dsccl.dla.mil>

DoD INDEX OF SPECIFICATIONS & STANDARDS (DODISS)

Home Page at: <http://www.dtic.mil>

IEEE RELIABILITY SOCIETY

Institute of Electrical and Electronics Engineers (IEEE)

445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331,

Tele: (800) 678-IEEE, FAX: (908) 981-9667.

http://www.enre.umd.edu/i3e/rs_hom.htm

Newsletter: http://www.enre.umd.edu/i3e/rsnl_hom.htm

MANUFACTURING TECHNOLOGY INFORMATION ANALYSIS CENTER (MTIAC)

Department of Defense (DoD) Information Analysis Center

Defense Technical Information Center (DTIC)

IIT Research Institute (IITRI).

<http://mtiac.iitri.com/>

NASA RELIABILITY AND MAINTAINABILITY STEERING COMMITTEE

NASA Center for Aerospace Information,

800 Elkridge Landing Rd., Linthicum Heights, MD 21090-2934,

Tele: (301) 621-0134, FAX: (301) 621-0100.

<http://www.hq.nasa.gov/office/codeq/rmhome23.htm>

OFFICE OF SECRETARY OF DEFENSE

COMMERCIAL & NONDEVELOPMENTAL ITEMS HANDBOOK, 5/96

<http://www.acq.osd.mil/es/std/ndi/>

OFFICE OF SECRETARY OF DEFENSE

DEFENSE ACQUISITION DESKBOOK

Home Page at: <http://www.deskbook.osd.mil>

Office of Secretary of Defense

Defense Standardization Program (Mil Spec Reform)

Home Page at: <http://www.acq.osd.mil/es/std/stdhome.html>

OFFICE OF SECRETARY OF DEFENSE

UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND TECHNOLOGY - OSD

Home Page at: <http://www.acq.osd.mil>

RELIABILITY ANALYSIS CENTER, - RAC

201 Mill St, Rome, NY 13440-6916

Tele: (315) 339-7089 David Nicholls

<http://rome.iitri.com/rac/>

ROME LABORATORY/ERSR

525 Brooks Rd., Griffis AFB, NY 13441-4505

<http://rome.iitri.com/rac/>

SOCIETY OF AUTOMOTIVE ENGINEERS - SAE

400 Commonwealth Drive, Warrendale, PA 15096-0001,

Tele: (412) 776-4970, FAX: (412) 776-5760.

Home Page at: <http://www.sae.org>

SOCIETY OF LOGISTICS ENGINEERS - SOLE

Home Page at: <http://www.telebyte.com/sole/sole.html>

SOCIETY OF RELIABILITY ENGINEERS - SRE

Home Page at: http://www.enre.umd.edu/sre/sre_home.html

Appendix D - Acronyms

1. BP MANUAL ACRONYMS

ACRONYM	DEFINITION
ABCR	As-Built Configuration Report
AEN	Automotive Electronics North America
AIA	Aerospace Industry Association
AIAG	Automotive Industry Action Group
ANSI	American National Standards Institute
APQP	Advanced Product Quality Planning - AIAG
AQC	Advanced Quality Concepts
ASQC	American Society for Quality Control
ATA	Air Transport Association
BOM	Bill of Material
C-of-C	Certification of Conformance or Compliance (Warrant)
CAD	Computer-aided Design
CAE	Computer-aided Engineering
CALS	Computer Aided Logistics Support
CCB	Configuration Control Board
CDR	Critical Design Review
CFP	Customer Furnished Property
CI	Configuration Item
CID	Commercial Item Description
CLS	Contractor Logistics Support
CM	Configuration Management
COTS	Commercial-Off-The-Shelf
Cp	Process Capability Index
CPI	Continuous Process Improvement
Cpk	Process Capability Index - Actual
CSA	Configuration Status Accounting
DCN	Design Change Notice
DFM/A	Design for Manufacturability/Assembly
DFMEA	Design Failure Mode and Effects Analysis
DMS	Diminishing Manufacturing Source
DoD	Department of Defense
DOE	Design of Experiments
DPAS	Defense Priority and Allocation System
DRBL	Design Release Base Line
DTC	Design to Cost
DV	Design Verification
ECN	Engineering Change Notice
ECO	Engineering Change Order
EIA	Electronics Industry Association
EO	Engineering Order
ESD	Electro Static Device
ESS	Environmental Stress Screening
FAR	Federal Acquisition Regulations

FCA	Functional Configuration Audit
FEA	Finite Element Analysis
FFFI (F ³ I)	Form, Fit, Function, Interface
FMEA	Failure Mode and Effects Analysis
FMECA	Failure Modes, Effects and Criticality Analysis
FOB	Free On Board
FTA	Fault Tree Analysis
GD&T	Geometric Dimensioning & Tolerancing
GFP	Government Furnished Property
GIDEP	Government and Industry Data Exchange Program
HPGL	Hewlett Packard Graphic Language
IEEE	Institute of Electrical and Electronic Engineers
IGES	International Graphic Exchange Specification
IPC	Institute of Printed Circuits
IPDT	Integrated Product Development Team
IPPD	Integrated Product/Process Development
IPT	Integrated Product Team
ISO	International Organization for Standardization
JACG	Joint Aeronautical Commanders Group
KC	Key Characteristics
LCC	Life Cycle Cost
M&P	Materials and Processes
MDAP	Major Defense Acquisition Program
MPCAG	Military Parts Control Advisory Group (DoD organization)
MPCL	Military Products from Commercial Lines
MRA	Material Review Authority
MRB	Material Review Board
MRPII	Manufacturing Resource Planning
MRR	Manufacturing Readiness Review
MTBF	Mean Time Between Failure
NGS	Non-Government Standard
NPMA	National Property Management Association
OEM	Original Equipment Manufacturer
OSD	Office of Secretary of Defense
PCA	Physical Configuration Audit (see PCV)
PCP	Program Control Plan
PCV	Physical Configuration Verification
PDM	Product Data Management
PDR	Preliminary Design Review
PFMEA	Process Failure Mode and Effects Analysis
PM	Program Manager
PN	Part Number
PO	Purchase Order
PPAP	Production Part Approval Process (automotive)
PPM	Parts Per Million
PPSL	Preferred Parts Selection List
PR	Purchase Requisition
PRR	Production Readiness Review
PV	Production Validation
QFD	Quality Functional Deployment
R&R	Repeatability & Reproducibility (Gage)

RAC	Reliability Analysis Center - Rome Laboratory
RBL	Requirements Base Line
SAE	Society of Automotive Engineers
SCD	Source/Specification Control Drawing
SHOVAR	Show Variance
SMD	Standard Military Drawing
SOLE	Society of Logistics Engineers
SOO	Statement of Objectives
SOW	Statement of Work
SPC	Statistical Process Control
SRE	Society of Reliability Engineers
SRR	System Requirements Review
TDP	Technical Data Package
TQM	Total Quality Management
TRR	Test Readiness Review
VE	Value Engineering
VHDL	VHSIC Hardware Descriptive Language
VHSIC	Very High Speed Integrated Circuit
VRI	Variability Reduction Instruction
VRP	Variability Reduction Program
WBS	Work Breakdown Structure