



ASSOCIATION CONNECTING
ELECTRONICS INDUSTRIES®

IPC-9199

Statistical Process Control (SPC) Quality Rating

IPC-9199

September 2002

A standard developed by IPC

2215 Sanders Road, Northbrook, IL 60062-6135

Tel. 847.509.9700 Fax 847.509.9701

www.ipc.org



Documents

Document Sharing Hub

The Principles of Standardization

In May 1995 the IPC's Technical Activities Executive Committee adopted Principles of Standardization as a guiding principle of IPC's standardization efforts.

Standards Should:

- Show relationship to Design for Manufacturability (DFM) and Design for the Environment (DFE)
- Minimize time to market
- Contain simple (simplified) language
- Just include spec information
- Focus on end product performance
- Include a feedback system on use and problems for future improvement

Standards Should Not:

- Inhibit innovation
- Increase time-to-market
- Keep people out
- Increase cycle time
- Tell you how to make something
- Contain anything that cannot be defended with data

Notice

IPC Standards and Publications are designed to serve the public interest through eliminating misunderstandings between manufacturers and purchasers, facilitating interchangeability and improvement of products, and assisting the purchaser in selecting and obtaining with minimum delay the proper product for his particular need. Existence of such Standards and Publications shall not in any respect preclude any member or nonmember of IPC from manufacturing or selling products not conforming to such Standards and Publication, nor shall the existence of such Standards and Publications preclude their voluntary use by those other than IPC members, whether the standard is to be used either domestically or internationally.

Recommended Standards and Publications are adopted by IPC without regard to whether their adoption may involve patents on articles, materials, or processes. By such action, IPC does not assume any liability to any patent owner, nor do they assume any obligation whatever to parties adopting the Recommended Standard or Publication. Users are also wholly responsible for protecting themselves against all claims of liabilities for patent infringement.

IPC Position Statement on Specification Revision Change

It is the position of IPC's Technical Activities Executive Committee (TAEC) that the use and implementation of IPC publications is voluntary and is part of a relationship entered into by customer and supplier. When an IPC standard/guideline is updated and a new revision is published, it is the opinion of the TAEC that the use of the new revision as part of an existing relationship is not automatic unless required by the contract. The TAEC recommends the use of the latest revision.

Adopted October 6, 1998

Why is there a charge for this standard?

Your purchase of this document contributes to the ongoing development of new and updated industry standards. Standards allow manufacturers, customers, and suppliers to understand one another better. Standards allow manufacturers greater efficiencies when they can set up their processes to meet industry standards, allowing them to offer their customers lower costs.

IPC spends hundreds of thousands of dollars annually to support IPC's volunteers in the standards development process. There are many rounds of drafts sent out for review and the committees spend hundreds of hours in review and development. IPC's staff attends and participates in committee activities, typesets and circulates document drafts, and follows all necessary procedures to qualify for ANSI approval.

IPC's membership dues have been kept low to allow as many companies as possible to participate. Therefore, the standards revenue is necessary to complement dues revenue. The price schedule offers a 50% discount to IPC members. If your company buys IPC standards, why not take advantage of this and the many other benefits of IPC membership as well? For more information on membership in IPC, please visit www.ipc.org or call 847/790-5372.

Thank you for your continued support.



ASSOCIATION CONNECTING
ELECTRONICS INDUSTRIES®

IPC-9199

Statistical Process Control (SPC) Quality Rating

Developed by the Statistical Process Control Subcommittee (7-22) of the
Process Control Management Committee (7-20) of IPC

Users of this standard are encouraged to participate in the
development of future revisions.

Contact:

IPC
2215 Sanders Road
Northbrook, Illinois
60062-6135
Tel 847 509.9700
Fax 847 509.9798



Documents
Document Sharing Hub

This Page Intentionally Left Blank

Acknowledgment

Any Standard involving a complex technology draws material from a vast number of sources. While the principal members of the Statistical Process Control Subcommittee (7-22) of the Process Control Management Committee (7-20) are shown below, it is not possible to include all of those who assisted in the evolution of this standard. To each of them, the members of the IPC extend their gratitude.

Process Control Management Committee	Statistical Process Control Subcommittee	Technical Liaison of the IPC Board of Directors
Chair Patricia J. Goldman PPG Industries Inc.	Chair Nicholas R. Watts Intel Corporation	Nilesh S. Naik Eagle Circuits Inc.

Statistical Process Control Subcommittee

Duane K. Allen, U.S. Navy	Colleen Halpine, Universal Circuits Inc.	Jaber (Joe) Khuri, U.S. Navy
Jason Bruenning, Plexus Corporation	Michael E. Hill, Dynamic Details, Inc.	Daniel Lewis, NSWC-Crane
Alan S. Cash, Northrup Grumman Corporation	Les Hymes, The Complete Connection	William R. Misiak, Raytheon E-Systems
David J. Curran, Agilent Technologies	James A. Ingersoll, Viasystems Technologies Corp.	Richard Pond, Schlumberger Industries Inc.
Joe Dihrkop, Defense Supply Center Columbus	Robert Johnston, Lucent Technologies, Inc.	William C. Thomas, Raytheon E-Systems
John F. Glaccum, Ethicon Endo-Surgery		Karen Walters, Consultant

Copyright IPC-Association Connecting Electronics Industries
 Provided by IHS under license with IPC
 No reproduction or networking permitted without license from IHS
 Full document details: IPC 9199 2002



Table of Contents

1 SCOPE	1	6.2	Definition of Process Targets and Limits.....	10
1.1 Objectives	1	6.3	Measurement System Evaluation and Control	11
1.2 Assessment Approach	1	6.4	Documented Work Instructions	13
1.2.1 Section 4 – SPC Objectives and Organization	1	6.5	Employee Training and Involvement in Process Data	14
1.2.2 Section 5 – Conditions for Statistical Process Control	1	6.6	Process Data Recording and Collection	15
1.2.3 Section 6 – Elements of a Statistical Process Control System.....	1	6.7	Traceability and Production Sequence Identification	16
1.2.4 Scoring Matrix.....	1	6.8	Subcontractor Performance Evaluation	17
2 APPLICABLE DOCUMENTS	1	6.9	Process Input Sequencing	18
2.1 IPC	1	6.10	Process Logs.....	19
2.2 International Organization for Standardization	2	6.11	Process Reliability.....	20
3 TERMS AND DEFINITIONS	2	6.12	Process Output Monitoring System	22
4 SPC Objectives and Organization	2	6.13	Process Control System	23
4.1 SPC Objectives.....	2	6.14	Short-Term Variability Assessment.....	24
4.2 Financial Motive for SPC.....	3	6.15	Long-Term Variability Assessment.....	26
4.3 Relationships	3	6.16	Communicating the Results of Process Analyses	28
4.4 SPC Organization	5	6.17	Customer Information System	29
4.4.1 Organizing for SPC Implementation	5	6.18	Internal SPC Audits	30
4.4.2 Strategic Planning	5	6.19	SPC Projects and Teams	31
5 CONDITIONS FOR STATISTICAL PROCESS CONTROL	6	6.20	Process Improvement, Optimization, and Troubleshooting	32
5.1 Management Support	6			
5.2 Understanding of SPC Tools and Methods	6	APPENDIX A	Example scoring system	33
5.3 Quality System	7	APPENDIX B	Process Control Plan – Example	34
6 ELEMENTS OF A STATISTICAL PROCESS CONTROL SYSTEM	8	APPENDIX C	Measurement System Evaluation and Control Verification Template	36
6.1 Process Documentation and Control Plan.....	8			

Statistical Process Control (SPC) Quality Rating

1 SCOPE

This document is intended to be a tool for a customer or supplier organization's internal audit group to assess a statistical process control (SPC) system against the requirements of IPC-9191. This document should be used by customers and suppliers of any size and for any commodity. This document should be used by trained evaluators. This tool can be used to perform an assessment of the use of SPC at both organizational and process levels.

The questions in this evaluation form are based on the guidelines for SPC implementation given in IPC-9191. IPC-9191 was developed to reflect the principals of SPC represented by the International Organization for Standardization (ISO) Statistical Methods Technical Committee's document: ISO 11462-1. Auditors should also have a fundamental understanding of statistics and their application in manufacturing.

This audit tool should be scaled to each individual organization's unique situation and resources by using the not applicable (N/A) response in areas of this quality rating.

1.1 Objectives The purpose of IPC-9199 is to provide examples of SPC implementation evaluation forms that may be used by customers and suppliers. The use of these forms should be mutually agreed upon between customer and supplier.

1.2 Assessment Approach The IPC-9199 evaluation format is a systematic assessment of each guideline section from IPC-9191 (Sections 4, 5 and 6).

1.2.1 Section 4 – SPC Objectives and Organization This section evaluates management for the following:

- How management sets objectives for SPC and communicates the objectives to employees.
- Managements' approach to determining the financial impact of the SPC program.
- The level of implementation of SPC as determined by the percentage of product specifications controlled with SPC vs. Quality Conformance Inspections.

1.2.2 Section 5 – Conditions for Statistical Process Control This section is an evaluation of management's support for SPC, including an SPC training plan and quality system infrastructure.

1.2.3 Section 6 – Elements of a Statistical Process Control System This section evaluates twenty elements of a SPC System for an individual process or processes being assessed. Each of the sections has two assessments: Organizational and Process. The organizational assessment determines the scope of the organizational policy in addressing the elements as defined by IPC-9191. The process assessment looks for evidence of implementation of each element at the process level.

1.2.4 Scoring Matrix Appendix A is an example scoring approach for an SPC system assessment. Each portion of Section 4 through Section 6 is assigned a specified number of points based on the total number of assessment areas shown. A percent completion is calculated based on the number of applicable elements verified as implemented on the process or processes under evaluation. The absolute score of an initial assessment should be used as a baseline. An organization or customer should set goals for continuous improvement of assessment scores.

2 APPLICABLE DOCUMENTS

The following documents form a part of this quality rating to the extent specified herein. Later issues of or amendments to these documents become part of this document unless otherwise stated. If a conflict arises, this document takes precedence.

2.1 IPC¹

IPC-T-50 Terms and Definitions for Interconnecting and Packaging Electronics Circuits

IPC-9191 General Guidelines for Implementation of Statistical Process Control

1. www.ipc.org

2.2 International Organization for Standardization²

ISO 11462-1 Guidelines for Implementation of Statistical Process Control

3 TERMS AND DEFINITIONS

Terms and definitions shall be as defined in IPC-9191 and IPC-T-50.

4 SPC Objectives and Organization

[NOTE: The tables contained in Sections 4, 5 and 6 of this document, in MS Word Template format, are available for free download from the IPC website using the following address: <http://www.ipc.org/html/downloads.htm> All descriptive narrative has been removed from the templates, leaving only the tables for electronic data input.]

4.1 SPC Objectives

Statistical Process Control has one or more objectives:

- (i) To increase knowledge about the process;
- (ii) To steer a process to behave in the desired way; and/or
- (iii) To reduce variation of final-product parameters or in other ways improve performance of a process.

The common economic objective of SPC is to increase good process outputs produced for a given amount of resource inputs.

Does the organization:

	Yes	No	N/A	Comments
1. Have stated objectives for the SPC program?	☐	☐	☐	
2. Are SPC objectives communicated to all employees?	☐	☐	☐	
3. Do SPC objectives include:	☐	☐	☐	
(i) Increasing knowledge of the process?	☐	☐	☐	
(ii) Steering processes in a desired way?	☐	☐	☐	
(iii) Variation reduction?	☐	☐	☐	
(a) Economic management of processes?	☐	☐	☐	
(b) Reducing variation around a target?	☐	☐	☐	
(c) Transferring variation to a control parameter?	☐	☐	☐	
(d) Assessing process behavior?	☐	☐	☐	
(e) Assessing process capability?	☐	☐	☐	
(f) Identification of assignable causes?	☐	☐	☐	
(g) Root cause analysis?	☐	☐	☐	
(h) Removal of assignable causes?	☐	☐	☐	
(i) Controlling and/or reducing random cause variation through process design?	☐	☐	☐	
(j) Cause and effect analysis?	☐	☐	☐	
4. Does the SPC strategic plan identify individual projects?	☐	☐	☐	
5. Are the projects supported by cross-functional teams?	☐	☐	☐	
6. Do project plans show evidence of objectives to minimize current quality conformance techniques with identification of cause-effect relationships between end product, in-process product and process parameters?	☐	☐	☐	

Organizational Verification Requirements <i>To receive credit for 4.1, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Documented SPC objectives			☐	
Evidence of communication and understanding of SPC objectives by employees			☐	

Section 4.1 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____

2. ISO documents available through ANSI, www.ansi.org

4.2 Financial Motive for SPC

The strongest motive for SPC is financial: to increase good process outputs produced for a given amount of resource inputs.

Does the organization:

	Yes	No	N/A	Comments
1. Collect producer costs such as cost of scrap, screening, rework, equipment repair, downtime, and outages? (a)				
2. Collect consumer costs incurred over the life cycle of the product (e.g., external failure costs)? (b)				
3. Estimate the amount of business and jobs lost because dissatisfied customers turn to competitors or refuse to pay a premium for perceived greater quality? (c)				
4. Estimate benefits to other parts of the organization, (such as design and development, marketing, production, installation, and servicing) from the feedback and information that SPC brings? (d)				
5. Quantify benefits to other parts of the organization from faster troubleshooting and greater potential for process or product innovation? (e)				

Organizational Verification Requirements <i>To receive credit for 4.2, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Evidence of collection and analysis of quality costs. Reference the type of costs in the above table.				
Evidence of management review and decision making from the quality cost analysis.				

Section 4.2 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____

4.3 Relationships

The general SPC objectives are shared both by traditional Shewhart control methods and by automatic process control based on a more complex model. The SPC elements can be used either to reduce variation in a process parameter or output or to transfer variation to an adjusted or manipulated process input (i.e., the chemical industry). The objective of reducing variation around target in final-product parameters is the same whether the process and/or product have specification limits. SPC helps to minimize efforts required to assure final product conformance to specification (i.e., screening, sorting, sample inspection, 100% inspection, and/or testing) in the following ways.

Does the organization:

	Yes	No	N/A	Comments
a) Identify cause and effect relationships between final product, in-process product (or process output), and process input parameters? (4.3.2a)				
b) Enable controls to be set up as early in the process as possible? (4.3.2b)				
c) Minimize process variation based on knowledge acquired from (a) and on control actions taken in (b) above? (4.3.2c)				



Part A Verification: Indicate the Percentage Completion of:

Process (Indicate Process Name)	4.3 (a) Evidence of identification of cause and effect relationships between final product, in-process product (or process output), and process input parameters.	4.3 (b) Evidence of enabling controls to be set up as early in the process as possible.	4.3 (c) Evidence of minimizing process variation based on knowledge acquired from (a) and on control actions taken in (b).	Sub- mitted	On File	N/A	Comments
Critical Process A							
Critical Process B							
Critical Process C							
Critical Process (indicate % for all major processes)							
Organization- wide Summary (all processes)							

Part B Verification: Depending on progress made implementing SPC on a particular project, a supplier may prove the product meets specifications with one or of a combination of the methods shown below.

Instructions for verification of specification validation methods: Count all specifications covering a critical product. As a percentage of the total specifications counted, how dependent is the organization on each of the following ways of assuring product quality:

Quality Assurance Methods	Percentage of Specifications using this Quality Assurance Method	Sub- mitted	On File	N/A	Comments
1. Quality conformance evaluations and acceptance sampling without feedback to the process (i.e., screening, sorting, and testing).					
2. Quality conformance evaluations and acceptance sampling with feedback (algorithmic or procedural) to the process.					
3. Final-product parameter monitoring and control.					
4. In-process product parameter monitoring and control.					
5. Process parameter monitoring and control, for those parameters identified as correlating with final-product parameters.					
TOTAL PERCENTAGE					

Section 4.3 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____



4.4 SPC Organization

4.4.1 Organizing for SPC Implementation

SPC implementation activities such as process data collection, process control, parameter correlation, and capability assessment/improvement should be performed on a project-by-project basis, prioritized in a rational, economic manner.

Does the organization perform SPC implementation:

	Yes	No	N/A	Comments
1. Through projects selected based on specific criteria?				
2. Through work on processes linked in a successive stream or product supply chain? (For example, this may be done by choosing a final product parameter and organizing SPC efforts focusing on one set of parameters, then moving to another set successively upstream in the supply chain.)				

Organizational Verification Requirements <i>To receive credit for 4.4.1, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Evidence of a prioritized SPC project List.				
Evidence of SPC implementation on processes linked in a successive stream or product supply chain				

4.4.2 Strategic Planning

An SPC strategic plan is required to provide a systematic approach to accomplish product control through SPC. The SPC strategic plan must be dynamic and adaptable to unpredicted and planned changes to production practices and techniques and management objectives.

Does the organization's strategic plan for SPC include:

	Yes	No	N/A	Comments
A documented strategic SPC plan?				
Has the plan been updated to reflect current situation?				
Does the SPC strategic plan address all the elements in IPC-9191?				
Does the SPC strategic plan identify individual projects?				
Do cross-functional teams support the projects?				
Do project plans show evidence of objectives to minimize current quality conformance techniques with identification of cause and effect relationships between end-product, in-process product and process parameters.				

Organizational Verification Requirements <i>To receive credit for 4.4.2, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
A documented SPC strategic plan				
Strategic SPC project list with objectives to minimize current quality conformance techniques with identification of cause and effect relationships between end-product, in-process product, and process parameters.				

Section 4.4 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____

5 CONDITIONS FOR STATISTICAL PROCESS CONTROL

5.1 Management Support

The supplier's management should document, implement, and maintain its continuing support for SPC.

Does the organization:

	Yes	No	N/A	Comments
a) Improve the process based on periodic review of both SPC results and audit reports? (The supplier should ensure that management SPC policy is understood, implemented, and maintained at all levels in the organization.)				
b) Use and improve data to drive decisions about the process?				
c) Support recording of and reaction to process disturbances and/or out of control points without penalty to the source of the report?				
d) Appoint and support SPC coordination responsibility?				

Organizational Verification Requirements To receive credit for 5.1, the following must be on file or accompany the completed system assessment.	Sub- mitted	On File	N/A	Comments
Evidence of management review of SPC results and audit reports. (5.1a).				
Evidence that the organization reviews performance of processes against the SPC objectives in 4.1. (5.1a)				
Evidence of an organizational policy or procedure that requires the use of data to drive decisions about the process. (5.1b).				
Evidence that the organization supports recording and reaction to process disturbances and/or out of control points without penalty. (5.1c).				
Evidence of an organizational coordinator whose role is to plan, implement, and maintain the SPC system. (5.1d).				

Section 5.1 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____

5.2 Understanding of SPC Tools and Methods

The supplier should design, implement, and review programs in support of SPC tools and methods.

Does the organization:

	Yes	No	N/A	Comments
a) Provide awareness in SPC tools and methods for all employees (including management) involved with SPC?				
b) Provide training to make SPC skills appropriate to employees' job functions and to their interaction with the process?				
c) Ensure sufficient expertise is available to understand the objectives, applications, and risks associated with the statistical and algorithmic control techniques chosen?				

Organizational Verification Requirements To receive credit for 5.2, the following must be on file or accompany the completed system assessment.	Sub- mitted	On File	N/A	Comments
Evidence of an organizational training program that provides sufficient resources to meet the objectives of 5.2 (a) through (c).				

Section 5.2 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____



Documents

Document Sharing Hub

5.3 Quality System

To help preserve the benefits of the SPC system, the supplier should seek to establish and maintain the infrastructure of a quality system, for example, as prescribed by applicable ISO 9001 requirements.

Is the organization's quality system certified or accredited to:

	Yes	No	N/A	Comments
ISO 9001				
ISO 9002				
QS 9000				
TL 9000				
Other - Specify _____				

If the organization is not certified to a quality system specified above, does the organization have a quality system in place to address:

	Yes	No	N/A	Comments
1. Management responsibility?				
2. Quality system?				
3. Contract review?				
4. Design control?				
5. Document and data control?				
6. Purchasing?				
7. Customer supplied product?				
8. Identification and traceability?				
9. Process control?				
10. Inspection and testing?				
11. Inspection and test equipment?				
12. Inspection and test status?				
13. Nonconforming product control?				
14. Corrective/preventive action?				
15. Handling/storage/packaging/delivery?				
16. Quality records?				
17. Internal quality audits?				
18. Training?				
19. Servicing?				
20. Statistical techniques?				

Organizational Verification Requirements <i>To receive credit for 5.3, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Evidence of certification to any of the quality systems shown above.				
Evidence a current quality system manual documenting 1 through 20 in 5.3.				

Section 5.3 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____



6 ELEMENTS OF A STATISTICAL PROCESS CONTROL SYSTEM

6.1 Process Documentation and Control Plan

The supplier should document the process, the system of measurement, and the system of controls in a Control Plan. This should be done at all important points in the process where form, fit, function, or suitability for use are altered. The supplier is recommended to consider cost characteristics (if available) of basic technological operations and to draw on cross-functional job experiences.

To ensure compliance with verification requirements in this section, the process control plan template such as that shown in Appendix B is recommended for implementation and assessment.

NOTE: The purpose of a process documentation and control plan is to clearly and concisely define the critical elements of the overall process control plan for each process.

Does the process owner(s):

	Yes	No	N/A	Comments
a) Construct a flow diagram, or other alternative, that identifies:				
1. Process inputs and outputs?				
2. Process flows?				
3. Process measurement points (with feedforward or feedback control loops, if appropriate)?				
4. Process return loops (for example, repair, rework, regrinding, reprocessing, purging, or rejections and dropout of transactions)?				
5. Process boundaries?				
b) Identify:				
• Potential process parameters?				
• In-process product parameters?				
• Final-product parameters?				
(Process parameters sometimes may affect product performance in ways not measurable or observable immediately after the operation occurs.)				
• Which of the following methods are used to identify process/product parameters?				
1. Engineering judgment.				
2. Controls applied downstream to measure process parameters whose effects are not immediately visible.				
3. Conformance testing, repeated periodically when designs or materials change.				
4. Functional testing or accelerated testing.				
5. A system for timely customer feedback of suitability for use on receipt of the product by the customer.				
6. Special process studies or experimentation.				
c) Assess how process and in-process product parameters may affect form, fit, function, and suitability for the customer's use; and how time and conditions of use either may interact with these parameters' effects, or may directly affect final product parameters?				
d) Define expectations for how the three sets of parameters -process, in-process product, and final-product parameters—may be related, to help identify omissions in the control plan?				
e) Identify what parameters are effective to measure, where, when, how often; identifying how the data should be used; identifying how the data should be retained if applicable; and by what job function's responsibility; and understanding why certain parameters are chosen? (For example, in automatic control, indirectly and directly controlled variables are distinguished.)				
f) Identify what remaining parameters can only be measured with attribute or count data as the result, or not measured at all, to help rank improvements to the measurement system?				
g) State in an out-of-control action plan what to do about out-of-control signals and/or process disturbances: reaction mechanisms, corrective actions, and responsibilities for action by specific job functions?				



Documents

Document Sharing Hub

Organizational Verification Requirements <i>To receive credit for 6.1, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Requirements for process owners to document a process flow diagram (6.1a).				
Requirements for process owners to document a process control plan (6.1b).				
Requirements for process owners to periodically update process control plans (6.1b).				
Requirements for process owners to assess how process and in-process product parameters affect form, fit, function, and suitability for the customer's use (6.1c).				
Requirements for process owners to define relationships between the three sets of parameters -process, in-process product, and final-product parameters, to help identify omissions in the control plan (6.1d).				
Requirements for process owners to identify what parameters are effective to measure. (6.1e).				
Requirements for process owners to rank improvements to the measurement system based on those parameters that can only be measured with attribute or count data (6.1f).				
Requirements for an out-of-control action plan (6.1g).				

Process Verification Requirements <i>To receive credit for 6.1, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Process control plan for specific product type that includes all of the elements in 6.1b through 6.1g.				
Process control plan for any major process that includes all of the elements in 6.1b through 6.1g.				

Section 6.1 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____



6.2 Definition of Process Targets and Limits

The supplier should document the target values and limits (and/or method(s) used to arrive at them) of the process parameter (or in-process product parameter) beyond which the process will produce unacceptable or uneconomic process outputs or final product parameters.

NOTE: The purpose of defining process targets and limits is clearly define process operating limits that will ensure acceptable product is manufactured.

Does the process owner(s):

	Yes	No	N/A	Comments
a) Quantify target values and operating limits, or identify them with a qualitative description or other appropriate sensory mechanism, such as a picture, photograph, master sample, reference sample, etc.?				
b) Review target values and/or operating limits, including evaluating their adequacy with respect to both customer needs and an understanding of the process?				
c) Identify problems that affect the setting of targets and limits? (This helps the supplier rank improvements to the customer feedback system or to the system that measures the accelerated life of a product.)				
d) Draw on cross-functional job experiences to set targets and limits, especially those job functions involved in setting or adjusting process control parameters or in responding to process disturbances?				

Organizational Verification Requirements <i>To receive credit for 6.2, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Requirements for setting target values and limits of process and in-process product parameters, and documenting methods used to arrive at them (6.2a)				
Requirements for periodic evaluation of process target values and limits (6.2b).				
Requirements for identifying problems that the affect the setting of targets and limits. (6.2c).				
Requirements for drawing on cross-functional job experiences to set targets and limits, especially those job functions involved in setting or adjusting process control parameters or in responding to process disturbances (6.2d).				

Process Verification Requirements <i>To receive credit for 6.2, the following must be on file or accompany the completed system assessment.</i>	Sub- mitted	On File	N/A	Comments
Documentation showing the target values and operating limits for process and/or in-process product parameters (6.2a).				
Evidence that the process owner periodically updates target values and operating limits (6.2b).				
Evidence that the process owner identifies shortcomings in targets and limits due to insufficient field tracking or other measurement problems (6.2c).				
Evidence that the process owner draws on cross-functional job experiences to set targets and limits, especially those job functions involved in setting or adjusting process control parameters or in responding to process disturbances (6.2d).				

Section 6.2 Scoring Summary:

Total questions in section applicable: _____ Total questions answered "Yes" : _____