



The Industry Voice for Workplace Solutions

Quality System Standard

BIFMA International
Date: May 24, 2004

©Copyright

Foreword..... iii

Acknowledgements..... iii

1 Scope, Purpose, and Implementation.....iv

2 Definitions.....v

3 Scoring Guidelines.....vii

 3.1 Audit Scoring Example.....vii

 3.2 Score Results.....vii

 3.3 Audit Record - Supplier Information Sheet.....viii

 3.4 Requirements for a Qualified Auditorix

4 Quality System.....1

 4.1 Management Responsibility.....1

 4.2 Quality System.....5

 4.3 Contract Review.....7

 4.4 Design Control.....8

 4.5 Document and Data Control.....11

 4.6 Purchasing.....12

 4.7 Control of Customer-Supplied Product.....14

 4.8 Product Identification & Traceability.....14

 4.9 Process Control.....15

 4.10 Inspection & Testing.....17

 4.11 Control of Inspection Measuring & Test Equipment.....18

 4.12 Inspection & Test Status.....19

 4.13 Control of Non-Conforming Product.....19

 4.14 Corrective & Preventive Action.....20

 4.15 Handling, Storage, Packaging, Preservation & Delivery.....22

 4.16 Control of Quality Records.....23

 4.17 Internal Quality Audits.....24

 4.18 Training.....25

 4.19 Servicing*.....25

 4.20 Statistical Techniques.....26

5 Quality System Scoring Profile.....27

6 Summary Comments.....28

7 Audit Corrective Action Response.....30

* This section of survey can be N/A (not applicable) if auditee does not perform their activities.

Foreword

The BIFMA Quality System Standard is a voluntary minimum quality system standard utilized within the Office Furniture Industry. This basic quality system standard is used by office furniture industry manufacturers and their suppliers. This standard was developed to provide an assessment of the supplier's quality system capabilities.

This document is based on important elements defined by ISO-9001 (2000 revision), incorporated into the ISO-1994 standard format of 20 elements. Not all elements of the standard will apply to all suppliers. Those elements that are exempt will be scored "NA" and will not be considered in the overall scoring for that supplier. To be considered for compliance, the only elements that can be exempt from the audit are Design 4.4, Customer-Supplied Product 4.7, and Servicing 4.19.

To promote acceptance of the audit results among the Office Furniture Manufacturers, Lead Auditors must have successfully completed an RAB (Registrar Accreditation Board) or International Accreditation Forum recognized Lead Auditor Training Program. In addition, participating Auditors must have successfully completed an RAB (Registrar Accreditation Board) or International Accreditation Forum recognized Auditor Training Program. Qualification should be noted on page vi and a copy of the training certificate attached to the audit. The Auditee (Supplier) is the accountable party who chooses a qualified second or third party auditor.

A great deal of time was spent in the development of the scoring system. It is used to provide insight into audit findings. Survey Scores for each element are based on a four-point scale. A minimum score of 3.0 in each of the audited elements is necessary for compliance. Scoring methodology for Level 1 through Level 4 is described in the Quality System Scoring Guidelines (page vii). Definitions for the terms used to define the various levels of scoring are listed on pages v and vi.

The Compliance period for this Standard is considered to be 3 years. Suppliers shall be re-assessed at minimum every 3 years using a Qualified Auditor as noted above.

Acknowledgements

BIFMA International thanks the members of the Quality Subcommittee of the Supply Chain Management Committee for the work in the development of the BIFMA Quality System Standard. For a current list of members of the Quality Subcommittee, contact BIFMA International at www.bifma.org.

Also, we extend our special thanks to Chairman Brian Bordewyk, Herman Miller, Inc. and the following subcommittee members for their assistance in the development of this document:

Joe Hoffman	American Seating Co.
Rick Amann	Grand Rapids Foam Rubber Co.
Brenda Helmer-Farrow	Haworth, Inc.
Bob Shulte	HNI, Corporation
John King	Irwin Seating
Lew Treadwell	ITW AIM Components
Rick Bischoff	Jireh Metal Products
Greg Jordan	Kimball International
Terry Spohr	Pent Assemblies
Lou Mintzer	Stabilus
Kathy Carter	Steelcase, Inc.
Dan Kallman	Steelcase, Inc.
Rick Lane	Suspa, Inc.
Michelle Cleveland	The Right Place Program
Ed Tolhurst	Valor Industries
Don Stephens	World Resources Partners

BIFMA Quality Standard Revision 9.3

1 Scope, Purpose and Implementation

Scope

- A quality system audit is a structured approach to learning about a business.
- This audit questionnaire includes elements of the business model defined in the 2000 revision version of ISO-9001.
- It profiles the business from initial customer negotiations through shipment and follow-up service.
- The audit looks at the business operating philosophy and how that philosophy is communicated.
- It looks at how management structures the business to carry out that philosophy.
- It evaluates how disciplined the operating system is in the day-to-day conduct of business.

Purpose

- The purpose of an audit is to assess the candidate's ability to meet customer requirements.
- A numeric scoring system is used to provide intuitive insight into the supplier's overall capability.
- Each element of the audit is scored. No item is left blank. Comments must be made justifying each element's scoring.
- The ISO-9001 business model is designed to protect the customer:
 - Does the candidate supplier clearly document and communicate customer requirements?
 - How does the supplier design their product or service to meet customer requirements?
 - How do they ensure that the product is built correctly in a cost effective and timely manner?

Implementation

- The reason for an audit will vary but the audit mechanics will normally include the following:
- The auditee will be asked to conduct a self-assessment using this Quality System audit document.
 - The auditee will be asked to provide the top-level documentation (policies & procedures) defining their quality system.
 - The lead auditor will form an audit team to develop a plan and conduct an on-site assessment.
- The general arrangements for conducting the audit should be determined in advance:
 - The time allowed to conduct the audit with an initial itinerary for meeting the deadline.
 - The establishment of an opening meeting with site executives and a time for the exit interview.
 - The supplier provides meeting rooms for the audit team and escorts to support team needs.
- All audit findings should be substantiated and evaluated for content and completeness:
 - During the shop tour observe general conditions, documentation and employee attitudes.
 - Verify all statements with documented evidence supporting what was said.
 - Use common sense. Do the answers pass the "reasonableness test" for this business?
- All audit observations should be briefly noted on the audit form while performing the audit:
 - Attempt to complete the audit at the end of the first day to identify follow-up requirements.
 - Caucus with team members to share observations and concerns to identify remaining issues.
 - Complete the audit and prepare for the exit interview.
- Conduct the exit interview and prepare the final report for supplier sign-off and acknowledgment:
 - Use the exit interview to share initial audit findings and to consider any supplier rebuttal.
 - The Lead Auditor will prepare a final report from input and discussion with team members.
 - Two copies of the final report will be submitted for sign-off with one copy to be returned.
 - Auditee and Lead Auditor signs the Audit Record-Supplier Information Sheet (page viii) documenting the audit occurred and if the supplier is compliant.
 - The auditee, at their discretion, is the only one authorized to distribute this report. The lead auditor retains all audit notes, examples, etc., from all auditors.

2 Definitions

Note: Refer to BIFMA PD-1 Industry Product Definitions for related terms not included in this standard. Otherwise, the common dictionary definition shall be used for terms not defined in this section or in BIFMA PD-1.

- 2.1 Design Input:** Documented product or process requirements. They should include applicable statutory or regulatory requirements and any contract review requirements. These specifications must be quantified, clear and unambiguous descriptions of product features, performance requirements and they should also identify desired financial goals and objectives.
- 2.2 Design Output:** Documented solutions (drawings, material and process specifications, bills of material, etc.) which have been demonstrated to meet design input requirements and can be used to perform final inspection verification and tests. These documents shall be reviewed and approved before release.
- 2.3 Design Review:** Planned critical assessments of proposed design solutions, which are normally conducted by representatives from all functional disciplines affected by the development project. The purpose is to provide robust solutions that consider both original criteria and the impact of the design on all downstream activities. The review should identify any previously unidentified implementation problems requiring further design consideration.
- 2.4 Design Validation:** Design validation is normally performed on final product and it follows successful design verification. It is an appropriate method used to demonstrate the product meets agreed upon customer needs and requirements. Multiple validations may be required if there are different intended uses for the same product.
- 2.5 Design Verification:** Records showing that design output meets design input. It documents the design criteria used to satisfy that need. In addition to design reviews, ISO-9001 identifies some acceptable verification options. Specific customer requirements may also apply.
- 2.6 Documented:** Written policies (level-1) procedures (level-2) work instructions (level-3) or forms (level-4) developed to control or manage the element being evaluated by the audit.
- 2.7 Effectiveness:** Available records confirm the process is accomplishing the desired end result.
- 2.8 Element:** A component of the audit section being evaluated. Any audit question (quality system requirement) that is being scored.
- 2.9 Evaluation:** An assessment or judgment on the value or worth of an element that is determined after careful consideration and analysis of the available implementation evidence vs. stated criteria.
- 2.10 Forms and Records:** Level-4 documents that are used to provide evidence that the element under review is implemented as described by the quality system and any supplemental quality planning.
- 2.11 Evidence:** Observations, records and verifiable input from supplier personnel, which should be summarized on the audit form to support the scoring shown.
- 2.12 Implemented:** The element under review is being carried out in accordance with the quality system documentation.
- 2.13 Incomplete Audit:** If any element cannot/or was not audited, the audit will be identified as incomplete. Audits will not receive a score and no determination of compliance will be issued. (Note: 4.4, 4.7, 4.19 can be N/A)
- 2.14 Measure:** An indication of the degree of agreement when compared to a standard. Examples: the extent of implementation relative to an applicable procedure, the degree to which an element achieves the desired end result or, comparisons of a quality system to the ISO standard (paper audit).

Definitions Continued

- 2.15 Overall Score:** A mathematical average of the averages. First, within each section, each element's (question's) score is averaged then, these 20 section averages (or however many sections have scores other than "NA") are averaged to determine the overall score.
- 2.16 Policy:** A plan or strategic course of action intended to influence and determine decisions, actions and the organization's understanding of the company's principles and operating standards. A policy is required for each element of ISO-9001. The combination of these policies forms a quality manual that provides an overview of the entire quality system and identifies functional responsibilities.
- 2.16 Procedure:** A written statement describing how to accomplish stated policies. It describes general process requirements, functional responsibilities and identifies the applicable documents required without providing detailed step-by-step instructions. These are tactical documents that contain the type of information that can be represented by a top-level flow chart.
- 2.17 Procedure Manual:** The combination of top-level procedures needed to explain the implementation requirements of the overall quality system common to the organization as a whole. Subordinate procedures and work instructions are normally held separately and managed by the function responsible for issuing them.
- 2.18 Quality Manual:** The compilation of policy statements needed to adequately describe the quality system. It should be as brief as possible and is normally less than twenty-five (25) pages.
- 2.19 Quality Planning:** Quality plans provide a mechanism to tie the specific requirements of a product, project or contract to existing quality system procedures. These plans identify and address concerns that can affect the quality of any process output. The process involved can be administrative, factory operations or service. Quality plans are either an overall system requirement or a supplement to it.
- 2.20 Quality System:** The organizational structure, procedures, processes and resources needed to operate the business and achieve effective quality management. It should be as comprehensive as needed to meet stated quality objectives.
- 2.21 Regularly Evaluated for Effectiveness:** The frequency of assessments determined to be necessary to verify compliance and ensure the desired end result is achieved. The frequency varies depending on the nature of the assessment: management reviews, internal quality audit plans (by section or element) and specific quality planning requirements. The frequency may be adjusted based on the conclusions of these assessments.
- 2.22 Scoring:** The scoring levels are shown below and they are a measure used to quantify the assessment of each scoring element (question) in the audit. The terms used are defined herein. Refer to page -iii- for more specific instructions.
- 2.23 Work Instructions:** Detailed step-by-step instructions for a specific job or task to ensure it is done correctly. They are designed to support applicable procedures and cover such things as manufacture of a part, completing an audit form, preparing a corrective action request or updating a control chart.

3 Scoring Guidelines

To ensure scoring consistency, follow the instructions for each category headlined below:

To receive a score of (4) the following is required:

- Evaluations of effectiveness must be recorded. These records will serve as objective evidence.
- The element is evaluated for effectiveness (achieving the desired result) at regular intervals.
- Records must be present to confirm the element is implemented as documented.
- The procedures or work instructions must be implemented as documented.
- The procedures or work instructions must fully address the element in question.

To receive a score of (3)-*minimum required*- the following is required:

- Records must be present to confirm the element is implemented as documented.
- The procedures or work instructions must be implemented as documented.
- The procedures or work instructions must fully address the element in question.

To receive a score of (2) the following is required:

- The element is either properly implemented or fully documented.
- If only product/process records exist, they must demonstrate the element is properly implemented.
- The procedures or work instructions must fully address the element in question.

To receive a score of (1) the following is required:

- There is little or no evidence the element is properly implemented or documented.
- Product/process records do not adequately confirm the element is properly implemented.
- Neither the procedures nor the work instructions fully address the element in question.

To indicate (NA) the following is required: (*only allowed for elements 4.4, 4.7 & 4.19*)

***Elements with the "NA" designation will not be used in scoring the section total.
The element is Not Applicable to the supplier's commodity or business or does not support the Office Furniture Industry.***

3.1 Audit Scoring Example for Section 4.11 (Control of Inspection Measuring & Test Equipment) of the Quality System Audit:

A Quality System auditor has reviewed the calibration status of a height gage that is being used by a manufacturing employee:

Scoring guidelines for the following results:

3.2 Score Results:

1. There is no evidence that a calibration program has been established or is being practiced.
2. A calibration program has been started but there are no established procedures or work instructions.
3. A calibration program is established and is being followed as specified in the documented procedures and work instructions. The height gage is properly calibrated and within schedule.
4. A calibration program is established, is being followed as specified in the documented procedures and work instructions and is reviewed by the departmental manager for effectiveness as well as by the internal audit team on a scheduled basis. The height gage is properly calibrated and within schedule.

3.3 Supplier Information Sheet

BIFMA QUALITY SYSTEM AUDIT RECORD - SUPPLIER INFORMATION SHEET

(Please Print)

Audit Date(s): _____

Audit Requested By: _____

Supplier Audited: _____ Site[s] _____

Street Address: _____

City, State, Zip _____

Scope of Audit: _____

Commodities: _____

Supplier Representatives:

Audit Team:

Lead Auditor: _____

Address: _____

Phone No.: _____

Auditor Qualifications _____

Audit Submitted By:

Audit Acknowledged By:

Lead Auditor Signature

Supplier Acknowledgment Signature

Clauses not applicable:

4.4 4.7 4.19

Audit is incomplete:

Reason: _____

Supplier score **meets** Quality System compliance:

Supplier score **does not meet** Quality System compliance:

Note: To request a Certificate of Conformance for audits meeting the requirements of this standard, return this completed form and a copy of the lead auditor's training certificate/qualifications to: BIFMA International 2680 Horizon Drive SE Suite A1. Grand Rapids, MI 49546.

This audit is not applicable to ISO-9000 registration.

Supplier Certificates
are available from BIFMA
For \$10.00 USD

3.4 Requirements for a Qualified Auditor

The requirements for a qualified auditor are:

Lead Auditor:
Must have successfully completed an RAB or International Accreditation Forum recognized Lead Auditor Training Program.

Auditor:
Must have successfully completed an RAB or International Accreditation Forum recognized Auditor Training Program.

Only a lead auditor can sign-off audit scores – page viii

4.1 MANAGEMENT RESPONSIBILITY CONTINUED

Organization (4.1.2)

Responsibility & Authority (4.1.2.1)

- d) Are quality responsibilities defined and documented for all personnel who manage, perform, and verify work affecting quality?

- e) Do their personnel have the authority, independence, and freedom to carry out their responsibilities for quality?

Look For:

- Job profile(s) or job description(s).
- Organization chart(s),
Yes No
- Procedures & work instructions.

Score:

- Written statements to that effect conveyed by policy manual, employee newsletter, etc.
- Responses from personnel (all depts/all shifts).

Evidence Supporting the Scoring Shown Above:

Resources (4.1.2.2)

- f) Has management identified and provided adequate resources and equipment?

Look For (Evidence Possibilities):

- A strategic plan for quality improvement:
 - Employee ownership for quality (philosophy).
 - A capital plan that addresses quality issues.
 - Quality related resources based on volume.
- Staffing levels for activities identified.
- Equipment purchases to plan.
- Key measureables are evaluated to identify resource needs.
- Does the employee understand their impact on quality and relevance of their activities to the customer?

Score:

Evidence Supporting the Scoring Shown Above:

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<input style="width: 50px; height: 15px;" type="text"/>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

4.1 MANAGEMENT RESPONSIBILITY CONTINUED

Management Representative (4.1.2.3)

g) Has senior management appointed a management representative to be responsible for quality system implementation and maintenance?

Look For:

- The announcement of the appointment.
- Defined job responsibilities:
 - Quality Policy Manual.
 - Job profile.

Score:

h) Is the role of the management representative clear and is it recognized by the organization?

- Quality System Procedures.
- Responses from personnel (all depts./all shifts).

Evidence Supporting the Scoring Shown Above:

Management Review (4.1.3)

i) Does senior management evaluate the quality system on a regular basis?

Look For:

- Meeting minutes:
 - Record of attendees (senior management?).
 - Comprehensive agenda.
- Evidence of follow-up and effectiveness on action items through the corrective action system.

Score:

j) Does senior management evaluate the quality system on a regular basis with results of the review driving toward continual improvement?

- Evidence showing the evaluation of the corrective action system – current status and trending.
- Key measurables are reviewed showing evidence of improvement and system effectiveness

k) The management review shall include the assessment of opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

- Evaluation of customer feedback data resulting in action items as appropriate.
- Goals are established to monitor / improve customer feedback scores.
- Records from management review shall be maintained.
- Relationship between policy and objectives with results.
- Employee suggestion system.
- Review of unstable processes (business, systems or manufacturing) / Action Plans
- Cpk analysis, scrap reporting, audit/containment results...etc.
- Relevance and status of corrective and preventive actions in relationship to quality policy.

Evidence Supporting the Scoring Shown Above:

Whole No. Scoring	4	=	This element is documented, implemented and regularly evaluated for effectiveness.
	3	=	This element is documented <u>and</u> it is implemented as documented.
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.
	1	=	Little or no evidence this element is addressed.
	NA	=	Not applicable (only 4.4, 4.7, 4.19)

4.4 DESIGN CONTROL CONTINUED

Design Input vs. Design Output (4.4.4-5)

- c) Does the supplier formally document design input (specification) requirements for comparison with design output documents?

- d) Does the supplier have an effective process for communicating design / product information with the customer?

Look For (Evidence Possibilities):

- Design input documentation:
 - Defined product features, function & testing.
 - Contract review requirements.
 - Regulatory & code compliance requirements.
- Design output documentation:
- Test results & document review before release.
 - Drawings, ECNs, material specifications.
 - Identification of critical characteristics.

- Design input and output communication with the customer:
 - Customer requirements for design inputs
 - Design output communication to customer

Score:

Evidence Supporting the Scoring Shown Above:

Design Review (4.4.6)

- e) Does the supplier conduct formal design reviews?

- f) Does the supplier evaluate designs for continual improvement?

Look For (Evidence Possibilities):

- Meeting minutes, design review checklists.
 - The scope of the review follows the project plan.
 - The meeting participants are appropriate.
 - Conclusions, problems, proposed solutions and follow-up requirements are documented.

- Review of similar product designs and the resulting test output.
- Indications that designs have been reviewed for design improvement against criteria (such as durability, capability, manufacture-ability, customer feedback data, etc.).
- Engineering changes

Score:

Evidence Supporting the Scoring Shown Above:

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.
	3	=	This element is documented <u>and</u> it is implemented as documented.
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.
Scoring	1	=	Little or no evidence this element is addressed.
	NA	=	Not applicable (only 4.4, 4.7, 4.19)

Section Overview: Because the quality system is constantly evolving, its documentation needs to be continually updated. This section reviews the proper management of these documents; their generation, approval, distribution (internal and external) and subsequent revisions. Confirm that the proper version is distributed in a timely manner and the reason for each revision is explained. Scoring should be deferred until a cross section of documents from different areas have been sampled with contract review, design control, process control and purchasing being the most problematic areas.

4.5 DOCUMENT AND DATA CONTROL

Document / Data Approval & Issue (4.5.2)	Look For (Evidence Possibilities):	Score:
a) How does the supplier control quality system documents and data?	<ul style="list-style-type: none"> • Document control procedures for: <ul style="list-style-type: none"> ○ Policy and executive level procedures. ○ Functional and departmental procedures. ○ Administration of contract files. ○ Purchase order revisions. ○ Important external documents. • Approval signatures by authorized personnel. • Master lists indexing & identifying revisions for: <ul style="list-style-type: none"> ○ Policy and procedures. ○ Engineering documents (drawings, BOM's). ○ Computer software and custom programs. • Comparable database demonstrations. 	<input style="width: 60px; height: 20px;" type="text"/>
b) Are the appropriate documents current and available to those operations essential for the proper functioning of the quality system?	<ul style="list-style-type: none"> • Apparent accessibility of documents. • Responses from personnel (all shifts). • Proper revision of all controlled documents. • Obsolete documents still on file are suitably identified per the procedure. 	<input style="width: 60px; height: 20px;" type="text"/>

Evidence Supporting the Scoring Shown Above:

Document & Data Changes (4.5.3)	Look For:	Score:
c) Are document changes recorded in the document or on an appropriate attachment?	<ul style="list-style-type: none"> • Records of change / revision to procedures, software programs, engineering documents, etc. 	<input style="width: 60px; height: 20px;" type="text"/>
d) Does the same person, function or group review and approve all changes to the quality system?	<ul style="list-style-type: none"> • Notification of changes; originator sign-off. 	<input style="width: 60px; height: 20px;" type="text"/>

Evidence Supporting the Scoring Shown Above:

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<input style="width: 60px; height: 20px;" type="text"/>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: A business cannot be fully understood until you consider the development and sophistication of its supply base. With the de-emphasis on vertical integration and the corresponding increase and dependence on out sourcing, subcontracting networks are becoming even more critical to the success of any business. Remember that this section covers more than material acquisition; it includes tools, equipment and subcontracted services such as calibration, trucking, maintenance and consulting. This section is concerned with the qualification and selection of those capabilities, the integrity of the specification documents and purchase order requirements, the ongoing assessment of the active supply base and any special access and monitoring privileges built into these contracts.

4.6 PURCHASING		
<p>Evaluation of Subcontractors (4.6.2)</p> <p>a) Does the supplier have a documented system for selection and evaluation of suppliers?</p> <p>b) Does the supplier maintain an approved supplier list?</p> <p>c) Does the supplier continually monitor and evaluate subcontractor performance?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Evaluation and selection (qualification) procedures. • An approved supplier list. • Supplier rating program. • Performance review records. 	<p align="right">Score:</p> <div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		
<p>Purchasing Data (4.6.3)</p> <p>d) Do the supplier's purchasing documents clearly describe the product or service ordered?</p> <p>e) Does the supplier review and approve purchasing documents prior to release?</p>	<p>Look For:</p> <ul style="list-style-type: none"> • Completed purchase orders. Do the orders selected for audit include: supplier name, quantity, part number, revision level, grade, approval signature and quality requirements? • Purchase order verification (sign-off) by authorized personnel. 	<p align="right">Score:</p> <div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 40px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 2px solid black; width: 40px; height: 20px; margin: 0 auto;"></div> <p align="right">Page 12 of 30</p>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: Customers typically provide material when the supplier is asked to perform a value added step in the overall process sequence. The customer is responsible for the integrity of the material supplied. The supplier is responsible for managing the material and accounting for its use. This element does not include custom tooling/fixtures, etc.

4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT		
<p>General 4.7</p> <p>a) How does the supplier control the verification, storage and maintenance of customer-supplied product?</p> <p>b) Does the supplier record and report the status of customer-supplied product that has been lost, damaged or found to be nonconforming?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Documented procedures. • Written communication to the customer. 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Section Overview: The supplier is an upstream resource to the customer and therefore subject to the customer’s own requirements for product identification and traceability. If the material is subject to product safety and environmental regulations, the requirement for traceability becomes more stringent.

4.8 PRODUCT IDENTIFICATION & TRACEABILITY		
<p>General (4.8)</p> <p>a) Does the supplier adequately identify product throughout all stages of production, delivery and installation?</p> <p>b) Does the supplier have a documented procedure to maintain the traceability of product when required by the customer?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Documented material identification procedures. • Accurate material identification; which may include quantity and content if specified by the procedure. • Traceability procedures. 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div> <p>Page 14 of 30</p>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: This section does not mandate that inspection and testing be performed. How conformance is demonstrated is established by the quality planning associated with design control and/or process control developments. Enhancements to this initial planning are incorporated from assessments for effectiveness based on customer feedback and process performance reviews. The outcome should represent the minimum verification required to ensure that process outputs satisfy specified requirements for the product; from the receipt of raw materials, through various stages of production, to any final inspection and testing required before the product is released for shipment. These requirements must be documented by either a quality plan or by procedures established by the quality system. Records need to be kept to profile the results against defined acceptance criteria.

4.10 INSPECTION & TESTING		
<p>Receiving Inspection & Testing (4.10.2)</p> <p>a) Does the supplier ensure that incoming material conforms to specified requirements?</p> <p>b) Does the supplier have an established mechanism for the recall and replacement of parts that were released for urgent production?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Documented acceptance criteria. • Test procedures. • Approved master samples • Incoming Inspection results. • Product identification and traceability instructions. • Records of material released for urgent production. • Positive recall instructions covering any exceptions. 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		
<p>In-Process Inspection & Testing (4.10.3)</p> <p>c) How does the supplier monitor and control production to meet specified requirements?</p> <p>d) Does the Supplier review inspection and test data to ensure product conforms to specification?</p>	<p>Look For:</p> <ul style="list-style-type: none"> • Inspection control plans and/or work instructions. • Product identification and test status documentation. • Inspection and test status reports. • Review of corrective actions, inspection results and the correlation of customer complaints to production data. 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
<p>Final Inspection & Testing (4.10.4)</p> <p>e) Does the supplier require completion of all specified inspection and tests prior to shipment?</p>	<ul style="list-style-type: none"> • Documented quality plans and/or work instructions. • Responses from operators and/or inspectors. <ul style="list-style-type: none"> ○ Can they demonstrate the inspection process? ○ Are they aware of customer complaints? • Inspection and test records. 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
<p>Inspection and Test Records (4.10.5)</p> <p>f) Does the supplier keep inspection and test records that clearly confirm the inspected product meets defined acceptance criteria?</p>	<ul style="list-style-type: none"> • Records for samples selected at random. • Responses from personnel responsible. 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 2px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: This section is concerned with the dependable verification of process output. The accuracy required to adequately perform any planned product inspection is determined by the criticality of the product characteristic as defined by the design control document. Similarly, process-monitoring devices (used for automatic process control or to manually adjust process variables) need to be calibrated in order to ensure a process can reliably meet and hold Cpk capability requirements.

4.11 CONTROL OF INSPECTION MEASURING & TEST EQUIPMENT

Control Procedure (4.11.2)	Look For (Evidence Possibilities):	Score:
a) Is the inspection, measurement and test equipment capable of meeting the required accuracy and is this capability traceable to national standards?	<ul style="list-style-type: none"> • Test records with evidence that measurement uncertainty is evaluated. • Evidence of traceability to national standards. • Serial numbers & calibration information on masters. • Specified environmental conditions. 	<input style="width: 50px; height: 20px;" type="text"/>
b) Does the supplier maintain calibration history records?	<ul style="list-style-type: none"> • Records which include: <ul style="list-style-type: none"> ○ Identification number. ○ Calibration date; interval between calibrations. ○ Master used; result (actual measurements). ○ The technician performing the calibration. 	<input style="width: 50px; height: 20px;" type="text"/>
c) Does the supplier maintain a master list of all inspection, measurement, test, and process control equipment needed to demonstrate conformance to requirements?	<ul style="list-style-type: none"> • Master list of all company-used equipment. 	<input style="width: 50px; height: 20px;" type="text"/>
d) Does the supplier ensure that calibration methods are appropriate?	<ul style="list-style-type: none"> • Documented qualification criteria. • Training records, certifications, etc. 	<input style="width: 50px; height: 20px;" type="text"/>
e) Is calibrated equipment identified with a label or other means of indicating status to the user?	<ul style="list-style-type: none"> • Description of the identification process. • Responses from personnel confirm they follow it. 	<input style="width: 50px; height: 20px;" type="text"/>
f) Does the supplier assess previous test results when inspection, measuring, & test equipment is found to be out of calibration?	<ul style="list-style-type: none"> • Established guidelines. • Records / evidence of assessment. 	<input style="width: 50px; height: 20px;" type="text"/>
g) Does the supplier ensure that handling, storage and preservation of inspection, measuring and test equipment is adequate?	<ul style="list-style-type: none"> • Documented storage requirements. Observe: <ul style="list-style-type: none"> ○ Storage, retrieval and operating methods. ○ Identification of out-of-calibration equipment ○ Appropriate safeguards on test equipment 	<input style="width: 50px; height: 20px;" type="text"/>
h) Does the supplier have documented procedures to assess & qualify calibration subcontractors?	<ul style="list-style-type: none"> • Approved supplier list. • Calibration certificates from approved suppliers. 	<input style="width: 50px; height: 20px;" type="text"/>

Evidence Supporting the Scoring Shown Above:

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<input style="width: 50px; height: 20px;" type="text"/>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: Good shop floor order management requires that order status is known, material is properly identified at each value added process point and material queues are minimized for optimum throughput. Shop floor orders should include predetermined inspection and test requirements; these requirements are an integral part of this overall process. No materials should move to the next process point without an indication the inspection and test requirements were performed and product is accepted.

4.12 INSPECTION & TEST STATUS		
<p>General</p> <p>a) Does the supplier identify inspection and test status from receiving through all stages of production and shipping?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Responses from involved personnel. • Control plans for inspection and testing. • Inspection approval records, that move with the product, such as: product identification tags, labels, routing cards, product markings, etc. 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Section Overview: When product does not meet inspection and test requirements, it must be tagged and removed from the normal production flow to ensure it does not get used accidentally. The nature of the nonconformance may allow the supplier to rework the material or use it as is. How these decisions are reached and who is authorized to make them must be predetermined. All rework material must be re-inspected before it is put back into production.

4.13 CONTROL OF NON-CONFORMING PRODUCT		
<p>General (4.13.1)</p> <p>a) Does the supplier identify and control nonconforming product?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Quarantine area or equivalent method. • Proper identification. • Records of nonconforming products/material and actions taken 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
<p>Review & Disposition (4.13.2)</p> <p>b) Has the supplier established an authority for the review and disposition of nonconforming product?</p>	<ul style="list-style-type: none"> • Some form of notification or announcement. • Responses from personnel (all depts./all shifts). • Criteria for documenting rework and repair. 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
<p>c) Does the supplier contact the customer for authorization to ship nonconforming material or alert them to the inadvertent shipment of these goods?</p>	<ul style="list-style-type: none"> • Notification records with customer acceptance. • Responses from personnel including Shipping and Customer Service personnel. 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
<p>d) Does the supplier submit all reworked or repaired? Material for re-inspection?</p>	<ul style="list-style-type: none"> • Responses from personnel. • Inspection and test records. 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
	1	=	Little or no evidence this element is addressed.	
Scoring	NA	=	Not applicable (only 4.4, 4.7, 4.19)	Page 19 of 30

Section Overview: Companies must continuously change and improve or they fail. The need to adapt to a changing marketplace environment will not allow them to simply stay the same. Customer complaints are a key input for the need to change. Product and process developments, initiated in response to the marketplace, require corresponding assessments on how effectively all twenty sections of the ISO-9001 quality system business model are able to manage those demands. The decisions reached on what needs to be done to address these issues are managed through the corrective action system that is established to fix the immediate problem, to develop measures that prevent its reoccurrence and to verify that those measures remain effective over time.

4.14 CORRECTIVE & PREVENTIVE ACTION		
<p>General (4.14.1)</p> <p>a) Does the supplier have a structured corrective action process, with appropriate records, which is used to document responses to system audits and any significant substandard performance trends vs objectives? Corrective Action Reports must include:</p> <ul style="list-style-type: none"> • problem identification • root cause analysis • long and short-term corrective action • verification & effectiveness <p>b) Does the supplier have a structured corrective action system that addresses purchased material?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Records which may include any of the following: <ul style="list-style-type: none"> ○ Internal Quality System Audit (IQA) results. ○ Customer complaints and product returns. ○ Scrap & rework. ○ Process and equipment capability studies. ○ Statistical Process Monitoring (SPM) data. ○ Corrective Action Reports • Nonconforming reports / communication with subcontractors • Corrective Action Reports. • Supplier performance data / results 	<p style="text-align: center;">Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
<p>Corrective Action (4.14.2)</p> <p>c) Are documented nonconformances routinely processed and identified for corrective action in a timely manner?</p>	<ul style="list-style-type: none"> • Corrective Action Requests (CAR) assigned to those accountable. • A corrective action database (manual or electronic) designed to monitor and document progress on all open corrective action requests (CARs). 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
<p>d) Does the supplier perform root-cause analysis of significant nonconformances and verify that process corrections are effective over time?</p>	<ul style="list-style-type: none"> • Assignment of responsibility for analysis. • Records of cause & effect analysis. • Evidence of subsequent validation of completed CARs. 	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 2px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: Producing a good part is the first step. Being able to deliver it in tact is the second. Typically, the potential for in-transit handling damage is the most common concern requiring adequate protective packaging. But, shelf life problems and resistance to environmental contamination also have to be evaluated. This may require special inventory management methods and/or the application of protective coatings in production.

4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

Handling Damage (4.15.2)	Look For (Evidence Possibilities):	Score:
a) Does the supplier have methods for handling product which prevent damage and deterioration?	<ul style="list-style-type: none"> • Evidence of handling damage. • Appropriate handling techniques. 	<input style="width: 50px; height: 20px;" type="text"/>
Storage (4.15.3)		
b) How does the supplier control receiving and issuing of product from storage?	<ul style="list-style-type: none"> • Appropriate work instructions. • Authorized personnel lists. • Inventory Control instructions (i.e. FIFO). 	<input style="width: 50px; height: 20px;" type="text"/>
c) Does the supplier have adequate storage areas and stock rooms to prevent damage and deterioration to parts and product?	<ul style="list-style-type: none"> • Storage facilities & warehouse methods practiced in the following areas: <ul style="list-style-type: none"> ○ Receiving. ○ Work-in-process storage. ○ Shipping. 	<input style="width: 50px; height: 20px;" type="text"/>
d) Does the supplier periodically conduct cycle counts for record accuracy and monitor the physical condition of the product in storage?	<ul style="list-style-type: none"> • Reporting condition of stored products; scrap outs? • Cycle count results vs. database records (%-error) to establish an assessment of inventory accuracy. 	<input style="width: 50px; height: 20px;" type="text"/>
Packaging (4.15.4)		
e) Are packaging materials and methods adequate to preserve product quality and provide identification?	<ul style="list-style-type: none"> • Conformance to customer packaging requirements. • Conformance to internal packaging specifications. 	<input style="width: 50px; height: 20px;" type="text"/>
Preservation (4.15.5)		
f) Does the supplier provide appropriate methods for preservation and segregation of product until title transfers to the customer?	<ul style="list-style-type: none"> • Documented storage requirements. • Evidence of storeroom practice. • Stated shelf life limitations. 	<input style="width: 50px; height: 20px;" type="text"/>
Delivery (4.15.6)		
g) Does the supplier protect product quality after final inspection and test?	<ul style="list-style-type: none"> • Conformance to packaging requirements. • Master List of approved carriers. • Contractual requirements from the customer. 	<input style="width: 50px; height: 20px;" type="text"/>

Evidence Supporting the Scoring Shown Above:

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<input style="width: 50px; height: 20px;" type="text"/>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: Quality records provide the feedback needed to keep the system viable. They indicate where process adjustments are required in the daily conduct of business and they establish the audit trail needed to facilitate system audits. Records provide an ongoing measure of system effectiveness and they are needed to verify the system is being implemented and maintained as documented. The checklist below identifies key system pulse points required by ISO-9001.

4.16 CONTROL OF QUALITY RECORDS		
General	Look For (Evidence Possibilities):	Score:
a) Are system records used to report performance trends to management and employees?	<ul style="list-style-type: none"> • Management Review minutes. • Employee communications media, charts and graphs. 	<input style="width: 50px; height: 20px;" type="text"/>
b) Are records kept in an environment that minimizes deterioration or damage and prevents accidental loss?	<ul style="list-style-type: none"> • Adequate storage for the defined retention periods. • Paper files: secure and properly identified, fire proof, protective folders, laminated copies? • Electronic media: virus protection, backup copies, hard copies of data and programs. 	<input style="width: 50px; height: 20px;" type="text"/>
c) Are records appropriate, accessible, legible, dated, identifiable, easily retrievable, and complete?	<ul style="list-style-type: none"> • Specified quality records by area or activity. • Evaluate examples from the checklist below. 	<input style="width: 50px; height: 20px;" type="text"/>

Evidence Supporting the Scoring Shown Above:

Quality Records Checklist

<u>ISO-9001 Required Records</u>	<u>Audit Observations</u>
4.1 Management Review(s)	• _____
4.2 Quality Planning	• _____
4.3 Contract Reviews	• _____
4.4 Design Reviews, Verification	• _____
4.6 Evaluation of Subcontractors (Approved Listing)	• _____
4.7 Customer-Supplied Product (documented losses)	• _____
4.8 Product Identification	• _____
4.9 Qualified Processes / Personnel	• _____
4.10 By-Passed Inspections Record	• _____
4.10 Inspection & Test Records	• _____
4.10 Authorized Inspection Personnel	• _____
4.11 Calibration Records	• _____
4.13 Rework & Acceptance Records (re-inspection)	• _____
4.14 Root Cause Analysis (record results)	• _____
4.17 Internal Audit Findings	• _____
4.17 Verification Audits	• _____
4.18 Training Records	• _____

Whole No. Scoring	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<input style="width: 50px; height: 20px;" type="text"/>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: A knowledgeable employee is a quality employee. For a process to be effective, both the employee and the associated equipment must be qualified. No employee should be expected to perform a job without receiving the necessary qualification training and demonstrating he or she can meet the specific job requirements. The criterion for a job or task is usually a combination of education, experience and specialized training. Training needs assessments must be performed periodically with appropriate training plans developed and implemented in response to the assessment. This typically can be accomplished as part of regular performance reviews or as part of an overall audit.

4.18 TRAINING		
<p>General</p> <p>a) Are training needs identified, documented and maintained for all personnel performing activities that affect quality?</p> <p>b) How does the supplier ensure personnel meet the specified training requirements?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Documented procedures. • Needs assessment. • Training plans & resources to implement them. <p>• Qualification requirements by job or task.</p> <p>• Training records for assigned personnel.</p> <p>• Corresponding personnel records (experience).</p> <p>• Job Descriptions</p>	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Section Overview: This is an often-misunderstood section of the quality system. The nature of the product may require highly specialized technical support that the customer cannot, or does not wish to provide. It may then become a contractual requirement, which would succeed any initial warranty obligation with documented procedures established for performing, reporting and verifying the service requirement.

4.19 SERVICING		
<p>General</p> <p>a) Does the supplier demonstrate compliance to specified service requirements?</p>	<p>Look For:</p> <ul style="list-style-type: none"> • Warranty agreements / policies. • Service records. • Contract Review records. • Qualification training. • Controlled service literature. • Calibration of needed service equipment. 	<p>Score:</p> <div style="border: 1px solid black; width: 60px; height: 20px; margin: 5px auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: When assessing this section, there is a tendency to limit the audit focus to what is being done. This section is really an extension of process control planning (section 4.9). There must be evidence that the need for statistics was considered and that any selection is an integral part of the quality planning process. This rationale should be documented and, when the decision is to employ some form of statistics, procedures written to implement and control the statistical techniques selected. As with all quality system procedures, the effectiveness of the statistical technique selected needs to be regularly evaluated to verify it is achieving the desired end result, which is effective process control.

4.20 STATISTICAL TECHNIQUES		
<p>Identification of Need (4.20.1)</p> <p>a) How does the supplier identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics?</p>	<p>Look For (Evidence Possibilities):</p> <ul style="list-style-type: none"> • Documented procedures. • Design and Process FMEAs. • Statistical needs assessment (selection criteria). • Decision tree analysis. 	<p>Score:</p> <div style="border: 1px solid black; width: 50px; height: 20px; margin: 0 auto;"></div>
Evidence Supporting the Scoring Shown Above:		
<p>Procedures (4.20.2)</p> <p>b) How does the supplier implement, control and evaluate the application of statistical techniques?</p>	<p>Look For:</p> <ul style="list-style-type: none"> • Quality Plan(s). • Quality Records (statistical). • Qualification Training records. • Ongoing assessment of the suitability of the statistical techniques employed. 	<p>Score:</p> <div style="border: 1px solid black; width: 50px; height: 20px; margin: 0 auto;"></div>
Evidence Supporting the Scoring Shown Above:		

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 1px solid black; width: 50px; height: 20px; display: inline-block;"></div> Page 26 of 30
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

Section Overview: This page should convey the audit team’s overall impressions of the supplier. It should profile their strengths as well as apparent opportunities for improvement. The comments here should facilitate the exit interview process and be consistent with the scoring shown. Genuine concerns should be expressed and the supplier should point out any areas where they feel the team misinterpreted what they saw. And finally, the supplier must provide corrective action using the form enclosed or their own form using internal corrective processes & documents.

5 Quality System Scoring Profile:

Overall Score:

Mgmt. Responsibility

4.1.1a	
4.1.1b	
4.1.2.1c	
4.1.2.1d	
4.1.2.2e	
4.1.2.3f	
4.1.2.3g	
4.1.3h	
4.1.3i	
4.1.3j	
4.1.3k	
4.1.4L	

Purchasing

4.6.2a	
4.6.2b	
4.6.2c	
4.6.3d	
4.6.3e	
4.6.4f	
4.6.4g	

Insp. & Test Status

4.12a	
-------	--

Non-Conf. Product

4.13.1a	
4.13.2b	
4.13.2c	
4.13.2d	

Quality System

4.2.1a	
4.2.2b	
4.2.3c	
4.2.3d	

Control of COM

4.7a	
4.7b	

Corrective and Preventive Action

4.14.a	
4.14.b	
4.14.c	
4.14.d	
4.14.e	
4.14.f	

Contract Review

4.3.2a	
4.3.2b	
4.3.3c	
4.3.4d	

Prod ID & Trace

4.8a	
4.8b	

Hdlg, Stor, Pkg, Del

4.15.2a	
4.15.3b	
4.15.3c	
4.15.3d	
4.15.4e	
4.15.5f	
4.15.6g	

Design Control

4.4.2a	
4.4.3b	
4.4.4-5c	
4.4.4-5d	
4.4.6e	
4.4.6f	
4.4.7g	
4.4.8h	
4.4.9i	

Process Control

4.9a	
4.9b	
4.9c	
4.9d	
4.9e	

Quality Records

4.16a	
4.16b	
4.16c	

Doc. & Data Control

4.5.2a	
4.5.2b	
4.5.3c	
4.5.3d	

Inspection & Testing

4.10.2a	
4.10.2b	
4.10.3c	
4.10.4d	
4.10.5e	
4.10.5f	

Internal Qual. Audits

4.17a	
4.17b	
4.17c	
4.17d	

Meas. & Test Equip.

4.11.2a	
4.11.2b	
4.11.2c	
4.11.2d	
4.11.2e	
4.11.2g	
4.11.2h	

Training

4.18a	
4.18b	

Servicing

4.19a	
-------	--

Statistical Techniques

4.20.1a	
4.20.2b	

Whole No. Scoring	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<input style="width: 50px; height: 20px; border: 1px solid black;" type="text"/>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

6 Summary Comments

Supplier Audited: _____ Date Audited: _____

Summary Comments: [Large empty table area for notes]

Table with 3 columns: Whole No., Scoring, and Description. Includes a legend for scores 4, 3, 2, 1, and NA.



7 Audit Corrective Action Response

The following form may be used for Audit Corrective Action or supplier may use existing forms to document corrective action.

USE ADDITIONAL SHEETS WHERE NECESSARY

Purpose: Provide a means of tracking supplier initiated, or customer required, corrective action measures to be implemented in response to issues identified by the audit.

Audit Impact: Upon successful implementation, this document may become a supplement to the original audit.

Initiator(s): _____

Assignee: _____

Problem Description		
Delegated To: _____		Date: _____
Containment Action:		
Response Date: _____	Effective Date: _____	Initiator Approval _____
Corrective Action		
Effective Date: _____		Initiator Approval _____
Root Cause		
Effective Date: _____		Initiator Approval _____
Preventive Actions & Verification Methods		
Effective Date: _____		Initiator Approval _____

Objective Evidence Has Been Reviewed

CAR Closed By: _____

Date: _____

Whole No.	4	=	This element is documented, implemented and regularly evaluated for effectiveness.	<div style="border: 1px solid black; width: 30px; height: 15px; display: inline-block;"></div>
	3	=	This element is documented <u>and</u> it is implemented as documented.	
	2	=	This element is documented <u>or</u> there is evidence it has been implemented.	
Scoring	1	=	Little or no evidence this element is addressed.	
	NA	=	Not applicable (only 4.4, 4.7, 4.19)	

END OF DOCUMENT