Energy Facility Contractors Group (EFCOG)
Supply Chain Quality Task Team
Supplier Evaluation Program

August 2008
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Mike Mason, EFCOG ISM Working Group Quality Assurance Subgroup Chair

Date

Paul Bills, Supply Chain Quality Task Team Lead

Date
Reviewers

Alice Lewis, Pacific Northwest National Laboratory
Art Reynolds, Parsons
Audrey Cooper, Fluor Hanford
Catherine Nesser, WIPP
Connie Arnwine, Oak Ridge National Laboratory
Corey Cate, Lawrence Livermore National Laboratory
Dave Tuttle, Washington Savannah River Company
Emily Wilson, National Security Technologies
Jerry Gutgsell, Los Alamos National Laboratory
John Zombro, Argonne National Laboratory
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Paul Bills, Idaho National Laboratory
Steve Stein, Brookhaven National Laboratory
Tony Vigil, BWXT Pantex
INTRODUCTION

EFCOG ISM Working Group QA Subgroup Supply Chain Quality Task Team (SCQTT) is comprised of representatives from Department of Energy (DOE) and National Nuclear Security Administration (NNSA) contractors' organizations. Each of these organizations procures various commodities that are used in both nuclear facilities and non-nuclear facilities. The SCQTT meets semiannually to network with other contractors, to share supplier information, and to address supplier and other supply chain quality issues that face the complex.

The SCQTT has noted that a number of DOE contractors continually evaluate the same suppliers, usually on a triennial basis. In order to reduce the duplication of effort by contractors and to free suppliers from continual evaluations that audit to the same or similar criteria, the SCQTT has established its own Supplier Evaluation Program (SEP). SCQTT has developed a standardized assessment program to evaluate suppliers of common commodities that have the potential to be used in both nuclear and non-nuclear facilities. The SCQTT has developed requirements matrices for the common commodities (available from the SCQTT Lead).

This SEP program adopts a typical standard audit protocol that includes audit scheduling, planning, performance, reporting, follow up and verification, and closure of the audit process. It also identifies lines of communication to ensure the proper reporting of audit/evaluation information. Implementation of this standardized methodology ensures that audits are documented and performed in a consistent manner by trained and qualified professionals. A trained and qualified Lead Auditor will lead these audits. The audit report is the product of this program. The audit report will be based on the applicable requirements identified in the audit plan. Where applicable the audit team will include Subject Matter Experts (SMEs) trained and qualified in areas applicable to the commodity being audited. Findings identified during the audit will be corrected and verified by an audit team member and accepted by the Lead Auditor. When completed, the audit report will be made available to DOE and NNSA contractors through the SCQTT. Each site that uses the results of a SCQTT audit will be responsible for reviewing and evaluating the evaluation results to ensure that the information meets their site specific quality and regulatory requirements and to make a determination regarding the extent to which the supplier evaluation information is relied upon.

1. PURPOSE

The SCQTT SEP is designed to ensure consistency when conducting evaluations of suppliers of commodities that have the potential to be used in both nuclear and non-nuclear facilities. Consistency is incorporated into this program by using requirements matrices that have been developed by SCQTT and by selecting joint audit teams that may include auditors and SMEs from multiple DOE and/or NNSA Contractors’ organization. By using shared resources, this program will reduce the number of audits performed of common suppliers, provide the benefit of using multi-site expertise, and reduce costs to suppliers by eliminating multiple audits of the same suppliers.

2. SCOPE

The scope of this SEP covers commodities that have the potential to be used in both nuclear and non-nuclear applications. This program does not include site-specific requirements and/or specifications; however, these documents may be provided by the sites to the Lead Auditor and auditors to be used as part of the audit preparation. The SCQTT has developed requirements matrices based on a national consensus standard.
3. DEFINITIONS

**Audit** - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

**Audit Checklist** - A listing of documents or questions that identify each element or area the evaluation is intended to address.

**Auditor** - Any individual in the organization who performs any portion of an assessment includes Lead Auditors, technical specialists, and others, such as management representatives and auditors in training.

**Audit Plan** - The Lead Auditor develop and document an assessment/audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

**Corrective Action** - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

**Document** - Any hard copy or electronic (text or graphic) information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined by NQA-1.

**Finding** - A direct departure from a procedural, regulatory, or contractual requirement.

**Lead Auditor** - A person certified as a Lead Auditor who is responsible for organizing, directing, and coordinating the conduct of an audit; reporting findings and observations; issuing the audit report; and evaluating the adequacy of responses.

**Objective Evidence** - Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

**Observation** - A weakness that, if not corrected, could yield a departure from a requirement.

**Observer** - An individual authorized by EFCOG SCQTT to observe an audit. An observer shall not actively participate in (i.e., perform auditor functions) or interfere with audit activities and shall be subject to the direction of the Lead Auditor while at the audited facility.

**Quality Assurance** - All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.

**Supplier** - Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.
Subject Matter Expert (SMEs) - An individual who has demonstrated technical expertise and knowledge in a specific subject area. The technical expert provides technical, system, and process information as an audit team member.

4. ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>DOE</td>
<td>Department of Energy</td>
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<tr>
<td>DOT</td>
<td>Department of Transportation</td>
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<tr>
<td>EFCOG</td>
<td>Energy Facility Contractors Group</td>
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<tr>
<td>ISIS</td>
<td>Integrated Supplier Information System</td>
</tr>
<tr>
<td>NNSA</td>
<td>National Nuclear Security Administration</td>
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<tr>
<td>POC</td>
<td>Point of Contact</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>SCQTT</td>
<td>Supply Chain Quality Task Team</td>
</tr>
<tr>
<td>SEP</td>
<td>Supplier Evaluation Program</td>
</tr>
<tr>
<td>SME</td>
<td>Subject Matter Expert</td>
</tr>
</tbody>
</table>

5. RESPONSIBILITIES

Supply Chain Quality Group Task Team Lead
When an audit is requested, the SCQTT Lead acts as the single point of contact (POC) for the maintaining and updating of the Annual Audit Schedule. The SCQTT Lead maintains the EFCOG SCQTT Common Supplier Listing. This listing is used to identify potential SCQTT-sponsored joint audits that can be performed to reduce costs to both DOE/NNSA contractors and suppliers.

Lead Auditor and Audit Team Members (as appropriate)
1. The Lead Auditor has ultimate responsibility for all phases of the audit and has the authority to make final decisions regarding conduct of the audit and determination of whether objective evidence indicates a finding and represents the audit team with the Supplier’s management.
2. During the course of an audit it will be the Lead Auditor’s responsibility with input from the Audit Team Members to determine if the Supplier has met the requirements identified in the audit plan. This decision can be made after all corrective actions have been completed and verified. During any phase of the audit if it is determined the Supplier’s program fails to meet the requirements identified in the audit plan, the Lead Auditor may terminate or postpone the audit after discussion with other team members.
3. Prepares the audit plan.
4. Schedules the audit in concert with the Supplier.
5. Issues the audit plan in a formal notification letter with a copy being sent to audit team members and the SCQTT Leader.
6. Requests the QA and applicable documentation along with and safety or security requirements from the Supplier.
7. Reviews the documents and distributes them to the appropriate team members. These documents will include any applicable SCQTT-approved requirements matrix.
8. Defines the requirements of each audit team assignment, i.e. QA, SMEs, briefs the team members on there respective assignments, and ensures team members have completed required reading of this document. When required reviews and approves additional checklist questions based on the audit team members’ review of the Supplier’s documentation.
9. During the audit conducts the entrance/exit meetings, daily caucus meeting with team members, and daily debrief meeting with Supplier’s management.
10. When compiling the audit report works with the audit team members in assembling the audit report. Ensure all findings, if applicable, are supported by appropriate documentation, and acts as an independent reviewer to ensure consistency.

11. Prepares and signs the audit report and letter, which may include requests for corrective action for findings identified during the audit and formally transmits to Supplier and audit team members.

12. When corrective action is requested in the audit report the Supplier will send the objective evidence for closure to the Lead Auditor. The Lead Auditor will review the documents and send them to the appropriate team member for review, verification and acceptance. When clarification of corrective actions is needed from the Supplier by the audit team member they work through the Lead Auditor to resolve that issue. If an at-site verification audit is required the Lead Auditor will assign the appropriate audit team member. Once accepted by the audit team member the Lead Auditor will sign the corrective action form.

Audit Team Members

1. Complete required reading of this document and sign the required reading form. The Lead Auditor will include with the audit documentation.

2. Review all appropriate documentation provided by the Lead Auditor and when appropriate provide additional checklist questions for approval by the Lead Auditor.

3. Perform their assigned activities and appropriately document all answers identified in the checklist with the appropriate objective evidence.

4. All findings are to be supported by appropriate objective evidence and are to be reported to the Lead Auditor during the daily caucus meetings prior to the daily debrief meeting with the Supplier’s management.

5. After the audit is completed the audit team members are to submit their checklist to the Lead Auditor within the time period defined by the Lead Auditor.

6. When corrective action is required as a result of the audit, the appropriate audit team member is to review and verify the documentation provided by the Supplier that would close the finding. When clarification of corrective actions or a verification audit is needed, the audit team member will work through the Lead Auditor to resolve.

7. Provide auditor qualifications and experience to the Lead Auditor for inclusion in the audit report.

Observer

An observer shall not interfere with the audit process and is to direct all questions and comments to the Lead Auditor.

6. WORK INSTRUCTIONS

Audit Preparation
The Lead Auditor is selected during scheduling process with input from participating Contractors and Supply Chain Quality Group members. The SCQTT Lead provides to the Lead Auditor the name, address, phone number and contact information of the supplier to be audited.

The SCQTT members and Lead Auditor review possible audit team members (i.e. SME in DOT, Welding, QA, etc., audit team members are selected based on their field of expertise and qualifications). The Lead Auditor contacts potential audit team members and obtains a commitment to participate on the audit (the SCQTT Lead may assist in this process). The Lead Auditor informs the SCQTT Lead once the team is assigned.
Audit Planning and Scheduling
The Lead Auditor prepares the audit plan (See appendix A for content); works with the supplier to determine a schedule for the audit and time of the entrance meeting and then confirms this with the audit team members; prepares the audit notification letter (See appendix B for content) that will be sent to the Supplier with the audit plan (see Appendix B) attached. When completed the audit notification letter and audit plan will be sent directly to the Supplier with copies going to the audit team members and the SCQTT Lead.

Audit Team Preparation
The Lead Auditor communicates with audit team members to ensure all questions are answered prior to the actual audit (this can be done by various conference calls); distributes applicable checklist to audit team members for review and audit preparation; receives the supplier documentation and ensures what has been received is what was requested; and distributed the supplier documentation to the appropriate audit team members.

Audit team members review documentation and determine if any new requirements are needed. If the checklist requires a revision audit team members will seek the approval of the Lead Auditor.

Conducting the Audit

Entrance Meeting
The Lead Auditor in coordination with the Supplier’s management conducts this meeting (explains the purpose of the audit and reviews the audit plan and identifies the lines of communication for the audit team); provides an Entrance Meeting Form (see Appendix C) to document those in attendance; and introduces members of the audit team and if an observer is in attendance explains their role.

Audit Team Members and Observers complete required reading of this document and sign the required reading form (Appendix D) at the Entrance Meeting.

A tour or walk through of the facility is not required, but is highly recommended. The object of the walk-through is to give the audit team members an overview of the Supplier’s operation and activities.

Performance of the Audit
During the daily caucus with the audit team, members provide objective evidence to support either a finding or observation during the day. The objective evidence will be discussed to ensure accuracy so they can be reported during the daily out briefing with the Supplier’s management.

During the daily debrief meeting with the Supplier’s management the Lead Auditor reports the day’s activities. The Lead Auditor will facilitate any discussions.

When a finding or observation has been identified and the Supplier takes immediate corrective action, the audit team member that identified the finding or observation may accept the corrective action and close the finding or observation during the audit. Findings or observations closed during the audit will be documented in the audit report.

Exit Meeting
The Lead Auditor in coordination with the Supplier’s management conducts this meeting (reviews the purpose of the audit); provides an Exit Meeting Form (see Appendix C) to document those in attendance; reviews with those in attendance all findings and/or observations identified during the
audit (all findings and/or observations should have already been identified to the Supplier so there are no “surprises” during the Exit Meeting); when possible provides the Supplier a draft copy of all findings and/or observations identified during the audit; identifies when the report will be issued to the Supplier, (e.g. 15-20 working days after the audit) or as deemed appropriate by the Lead Auditor; when applicable, and in agreement with the Supplier’s management, will identify when the corrective action will be expected after receipt of audit report.

The Lead Auditor will determine on or before the exit meeting, based on daily caucus’s and debrief meetings with the Supplier, if the findings and/or observations identified during the audit will meet the requirements identified in the audit plan. This is a crucial point in the audit because if the results of the audit show that the findings identified are of such an extent that they cannot be corrected in a reasonable amount of time the Lead Auditor must determine if the requirements identified in the audit plan are met.

**Audit Report and Letter**
The audit report (see Appendix E) and letter (see Appendix F) are prepared by the Lead Auditor with assistance from the audit team members. If there are questions concerning the audit they are to be directed to the Lead Auditor.

Completed Checklist - Checklists are to be completed and in an electronic form (i.e., pdf file). Each checklist used during the audit will be completed with the appropriate information answering the question using the objective evidence obtained during the audit. It should also include references to program documents in support of the requirements.

Any noteworthy practices may also be identified in the audit report.

**Corrective Action**
Each finding and observation identified during the audit will be documented on an audit finding/observation report form (see Appendix G). The supplier is to provide objective evidence that the finding has been corrected and implementation of that corrective action has been validated. When corrective action requires longer than the agreed upon time, the Supplier will provide a corrective action plan as to how and when the finding will be resolved.

**Audit Follow-Up**
The Lead Auditor receives the objective evidence from the Supplier for all findings identified during the audit. At this time the Lead Auditor will review objective evidence supplied for completeness and forward them to the appropriate audit team member for review.

The audit team member is to review the objective evidence submitted by the Supplier and determine if the corrective action taken effectively closes the finding. If more information is required to close the finding the audit team member works through the Lead Auditor to get this additional information from the Supplier.

When appropriate the audit team member may have to travel to the Supplier’s facility and verify that the actions taken to close the finding have been properly implemented. This action is agreed upon between the Lead Auditor and the audit team member. When an on site verification is required the Lead Auditor works with the Supplier and audit team member to schedule site visit.

When the audit team member is satisfied with the information provided he or she signs the audit finding/observation report form (corrective action verified by) and informs the Lead Auditor.
When the Lead Auditor receives notification from the audit team members that all findings have been successfully addressed, the Lead Auditor signs the audit finding/observation report form accepting the corrective action taken and closes the finding.

**Audit Closure**

Audit closure is completed by the Lead Auditor. After the audit team has completed their review of all the corrective action and verified implementation and the audit finding/observation report forms have been signed the audit is ready to close.

The audit closure letter acknowledges the Supplier for allowing the audit to take place, it also states that the corrective actions taken and/or planned are acceptable and attaches the signed audit finding/observation report forms to the letter. The closure letter identifies the QA program elements the Supplier is approved for. The letter also states that the complete audit report will be shared with other DOE/NNSA contractors upon request.

The audit closure letter (see Appendix H) formally closes the audit and is sent directly to the Supplier by the Lead Auditor with copies going to the audit team members and the SCQIT Lead for distribution. The following documents are required for entering audit information in the Integrated Supplier Information System (ISIS):

- Notification Letter (unless justification is entered in the evaluation history field of the ISIS record – e.g., lack of lead time)
- List of Entrance and Exit meetings’ attendees (separate attendance form or cited in the Audit Report and/or Audit Report Cover Letter)
- Audit Checklist (scan handwritten documents)
- Audit Report Cover Letter and/or Audit Report
- Auditee’s Response Letter *
- Response Evaluation Letter *
- Close-Out Letter
  * Not required if there are no Findings
Appendix A – Sample Audit Plan

**Audit Number:** [Lead Auditor assigns this number using contractor’s site-specific number log if available; if not assign a number using the calendar year, site name, sequential number (e.g., 2008-ORNL-001)]

<table>
<thead>
<tr>
<th>Contractor (include point of contact information):</th>
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<tr>
<th>Location of Audit:</th>
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<tr>
<th>Dates of Audit:</th>
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<th>Audit Team Members:</th>
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<th>Audit Scope:</th>
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<th>Technical Requirements:</th>
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<th>Approved By:</th>
<th>Date:</th>
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Appendix B – Sample Notification Letter

Date

Company’s Representative
Company’s Name
Address

Dear Mr./Ms./Dr.:

PLANNED QUALITY ASSURANCE AUDIT OF WIDGET EXPRESS CORPORATION ON SEPTEMBER 15-16, 2005

As agreed in an earlier discussion, an audit at your facility is scheduled for September 17, 2005. The purpose and scope of the audit is to determine if Widget Express Corporation has an implemented quality assurance/technical program to (specify requirement criteria). Lead Auditor (name, site represented) and IM Sidekick (Auditor, site represented) and UR Technical (Technical Auditor, site represented) will be the Representatives for this audit. The entrance meeting is scheduled for September 15, 2005, at 8:30 a.m., and the exit meeting is tentatively scheduled for September 16, 2005, at 2:00 p.m. See the attached audit plan for additional information.

Please ensure that adequate facilities are available both for conducting an entrance and exit meeting and for the audit team to caucus and review documents. Please ensure all appropriate documents are available for the auditor’s use during the audit. Notify the appropriate cognizant management and other appropriate personnel of the proposed audit schedule.

Please provide an uncontrolled copy of your Quality Assurance Manual to (insert the name, address or email of the Lead Auditor where these documents are to be sent.)

The results of this audit may be shared within the DOE/NNSA complex.

If you have any questions, please call me at (xxx) XXX-XXXX.

Sincerely,

Lead Auditor

cc: Audit Team Member(s)
    EFCOG SCQTT Lead
## Appendix C – Entrance and Exit Meeting Form

### Entrance/Exit Meeting

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Email address</th>
<th>Work Phone No.</th>
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</table>
Appendix D – Required Reading Completion Form

Note: This form is to be completed and signed by the Audit Team Member and/or Observer then presented to the Lead Auditor prior to conducting the audit.

<table>
<thead>
<tr>
<th>Name:</th>
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<table>
<thead>
<tr>
<th>Company:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>I have read and understand my responsibilities per my assigned role (i.e., Team Member, Observer) as described in the above document.</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature:</th>
</tr>
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<td></td>
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| Date:                                                                    |
|                                                                          |
Appendix E – Audit Title Page and Report

Department of Energy (DOE)
Energy Facility Contractor’s Group (EFCOG)

Supply Chain Quality Task Team Audit

of

Supplier’s Name
Address

Audit No. XXX-XXX-01

Audit Date: XX-XX, XXXX

This document is subject to being shared with other Department of Energy (DOE)
Government Owned Contractor Operated facilities; however, it is not approved
for release to the public. Therefore, the information contained in this document is
not to be disclosed outside of the DOE complex.

[Add Lead Auditor’s site-specific disclaimer information as appropriate.]
Appendix E – Audit Title Page and Report (continued)

Company:

Address:  

Telephone No.:

Evaluation Date(s):  

Report Date:

Team Members:

Contact:

INTRODUCTION

Note the evaluation purpose and scope if it has not already been addressed in the notification letter.

Personnel present during the entrance and exit meeting are as follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Entrance</th>
<th>Exit</th>
</tr>
</thead>
</table>

SUMMARY OF RESULTS

Provide the number of findings and observations.

There were two findings and one observations noted during the course of the At-Site Evaluation.

FINDINGS

A finding is a direct departure from a procedures, regulatory, or contractual requirement. It should be understood that any lack of a finding in a specific area is not considered an indication that deficiencies do not exist. The company should continue its own evaluations to ensure compliance to the (add criteria) and internal QA program requirements.

REQUIREMENT:

FINDING 1:

OBSERVATION:

An observation is a weakness that, if not corrected, could yield a departure from a requirement.

OBSERVATION 1:
Appendix F – Audit Report Letter

Date

Company’s Representative
Company Name
Address

Dear Mr./Ms./Dr.:

QA AUDIT OF WIDGET EXPRESS CORPORATION PERFORMED ON SEPTEMBER 15-16, 2005

Thank you for the cooperation extended to the audit team during the subject audit. The management system was documented and effectively implemented to most of (insert evaluation criteria) requirements; exceptions are noted in the attached audit report.

The audit team requests that a written response to each (finding or observation) be made within 20 working days after receipt of this report. The response must include identification of the root cause for each deficiency/finding as well as a description of the corrective action taken (or being taken) to correct immediate problems and to prevent future occurrences, and the date completed or scheduled to be completed. In addition, please identify any lessons learned as a result of this evaluation.

Resolution of the identified findings and objective evidence of implementation will give the audit team the right to enter Widget Express Corporation into the Integrated Supplier Information Systems (ISIS) as having an implemented QA program to (National/International QA Program).

If you have any questions, please contact me at (XXX) XXX-XXXX.

Sincerely,

Lead Auditor

IMC/ATL/XXX

Attachment

cc: Audit Team Members
EFCOG SCQTT Lead
### Appendix G – Sample Finding and Observation Report Form

**Audit Finding/Observation Report Form**

<table>
<thead>
<tr>
<th>Audit No.</th>
<th>Finding No.</th>
<th>Observation No.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lead Auditor</td>
<td></td>
</tr>
</tbody>
</table>

**Audited Organization**

**Person(s) Contacted**

**Auditor(s)**

**Requirement**

**Finding/Observation (as Indicated Above)**

**Response Required**

- [ ] Yes
- [ ] No

**Acknowledged By**

**Date**

**Corrective Action**

**Scheduled Completion Date**

**Signature/Date**

**Corrective Action to Preclude Recurrence**

**Scheduled Completion Date**

**Signature/Date**

**Lead Auditor Concurrence With Proposed Corrective Actions**

**Date**

**Corrective Action Verified By**

**Date**

**Lead Auditor**

**Date**
Appendix H – Closure Letter

Date

Company’s Representative
Company Name
Address

Dear Mr./Ms./Dr.:

CLOSE-OUT OF QA AUDIT OF WIDGET EXPRESS CORPORATION PERFORMED ON SEPTEMBER 15-16, 2005

Thank you for the final corrective action response to the subject at-site evaluation. Your response has been deemed acceptable and this at-site evaluation is considered closed.

The audit team will be entering Widget Express Corporation into the Integrated Supplier Information System (ISIS) as having an implemented Quality management system to (National/International QA program).

If you have any questions, please contact me at (XXX) XXX-XXXX,

Sincerely,

Lead Auditor

IMC/ATL/xxx

cc: Audit Team Member(s)
    EFCOG SCQT Lead