VSRA QA Audit Training: Auditee Module

Quality Auditor Training
Introduction

Purpose:

To provide a transferrable system for conducting audits on eligible companies in compliance with NSI 009-04, that will facilitate consistency, reduce volume and increase quality and efficiency in the audit programs.

Quality Auditor Training
Introduction

History:

The VSRA Quality Assurance Audit program was implemented in 2001 as a mechanism to improve the efficiency and substance of audits of companies that are subject to the audit controls of companies that fall under the auditing umbrella of the Navy Ship Support Activity. The program became the standard for audits that would be accepted by the shipyards, eliminating the need for companies to have multiple audits by different ship repairer companies who sub-contract their services. In 2012, the determination was made by the QA Committee to conduct its own internal audit of the program, with the purpose of updating it and creating a system for training and continuous improvement.

References

- ISO 9001: 2008 Standard
- NAVSEA Standard Items
- VSRA QA Audit Documentation

Responsible Parties

- The VSRA Quality Assurance Committee is responsible for approving the program.
- The VSRA Quality Assurance Committee Chairman is responsible for overseeing the program.
- The VSRA Quality Audit Subcommittee is responsible for reviewing the program, making recommendations for improvement at planned intervals, and maintaining an auditor training program.

Responsible Parties

- VSRA Ship Repairers, MSRs, ABRs, etc., that are audited by NSSA, SPAWAR, NAVSEA or NAVSSES directly, serve as Auditing Companies. Auditors must meet specific qualifications and are expected to complete their assigned Audits in a timely manner, with a helpful attitude. The goal is success, consistency and continuous improvement.

Responsible Parties

- VSRA Subcontractors and Suppliers that provide, or could provide, services which fall under the requirements of 009-04 are Audited Companies. They are expected to complete the Audit Pre-Interview, work in a timely manner of becoming a VSRA Member to schedule the Audit within 90-days, or within 60 days of the audit due date based upon the completion date of the last successful audit. Auditee must be prepared for the Auditor to expedite the process as much as possible, without diminishing the quality of the review.

(Mostly VSRA Subcontractors, however some VSRA Suppliers might fall into this designation, in which case they would become part of the VSRA Sub-Contractor Membership group. Future/new members who fall into the Audited Company designation would automatically be classified as Sub-Contractors at the start of their membership)

Auditing Company Qualifications:

- VSRA Member Company in good standing and
- Is designated as a Master Ship Repair (MSR), Large Ship Repair/Ship Repairer (SR), Agreement for Boat Repairer (ABR), Alteration Installation Team (AIT), Indefinite Delivery/Indefinite Quantity (IDIQ) and
- Has a current completed NSSA, SPAWAR, NAVSEA or NAVSSES audit or considered on an individual basis and
- Conducts their assigned VSRA audits

Auditor Person Qualifications:

- Employed by a VSRA Qualified Auditing Company* and
- Nominated by the company they work for and
- 2 years in an audited environment** with demonstrated examples of participating in, preparing for or being subject to an audit system and
- Attend VSRA Auditor training and
- Assist in one audit under a certified auditor upon completion of the VSRA Auditor training and
- Complete the audits they are assigned

* Auditors who work for other companies may appeal to the QA Committee to be a VSRA Auditor

** The person is not required to have the full two years in a QA Department, but must have held a leadership position that included responsibility for and direct experience with Audits.

Designated Audited Company

- Does not meet the criteria to be a VSRA Qualified Auditing Company
- Performs or could perform ship repair work that is subject to the requirements of 009-04

VSRA QA Review Sub-Committee

The QA Review Sub-Committee is appointed by the QA Committee to effect the following:

- Conduct an Annual Review of the QA Checklist to keep the content relevant and efficient.

Learning Objectives:

1. Understand the intent, purpose and use of the VSRA Audit Program
2. Understand and be able to describe elements of the QA documents
3. Understand and be able to utilize the on-line QA System

Special Terminology

Audit: Systematic, independent and documented **process** for obtaining **audit evidence** and evaluating it objectively to determine the extent to which **requirements** are fulfilled

Quality: Degree to which a set of inherent **characteristics** fulfills **requirements**

Transferrable: A common industry audit that when completed once under a VSRA approved auditor is acceptable by VSRA-member ship repairers as fulfilling the requirements for all.

Record/Document – results achieved that provide evidence of activities performed. Examples include specifications, procedure documents, drawings, reports, standards.

Objective Quality Evidence (OQE): Records, statements of fact or other information which are relevant and verifiable

Process: A set of interrelated or interacting activities which transforms inputs into outputs

Requirement: Need or expectation that is stated, generally implied or obligatory

Characteristic: A distinguishing feature

Quality Management System – Required elements include:

- Documented statements of a quality policy and quality objectives
- A quality manual
- Documented procedures required by ISO 9001:2008 (six topics) and NAVSEA Standard Item 009-04 (7 topics)

Critical: Any of the required elements listed in the Quality Management System

Satisfactory (SAT):

- Zero Major Findings
- No more than four (4) minor section findings
- Unlimited number of observations are allowed

SAT Action: Issue letter to Audited Company as deemed appropriate

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Unsatisfactory (UNSAT):

The audited company's system is not in general compliance with the requirements of the applicable specification. Systemic deficiencies were observed, which render the QMS non-compliant. If one mandatory system requirement is systemically deficient, then the QMS shall be rated unsatisfactory (UNSAT).

- One or more Major Findings AND/OR
- 5 or more Minor Section Findings

UNSAT Action: *Mandatory* Review and Letter not Issued unless:

- Audited Company responds to their Findings, AND
- submits documentation demonstrating those Findings have been resolved by an approved Auditor prior to the next audit date, AND
- Verifies the Auditor has cleared them as Resolved in the VSRA Audit System

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Finding

Corrective Action – Action taken to identify the root cause of a detected **nonconformity** and to put systems in place to prevent recurrence

Nonconformity – Non-fulfillment of a **requirement**

Correction – Action taken to eliminate a detected **nonconformity**

(Note the distinction between a **Corrective Action** and a **Correction**)

Major:

A Major Finding is Issued when the following applies:

- Complete lack of an element of the Quality Management System (QMS) as evaluated against the requirements (regulatory or contractual)
- A deficiency in the QMS which could result in catastrophic material failure
- Previous Minor Finding not corrected since last Audit

Minor:

- Violation of a requirement of the QMS with fewer than 5 instances involving the same section.

Observation

- An instance that is not a direct violation of a QMS requirement, but could be a potential risk to the quality system and/or to product conformance.
- Suggested opportunity for improvement
- Comments by the Audit Team
- **Positive examples of the company's system**

Note: Observations will be included in the audit report, but do not require a response from the Audited Company.

Planning an Audit: Outline

1. Pre-Audit Questionnaire
    1. Auditee Completes and Submit
    2. Auditor Review
2. Preparation Checklists
    1. Auditee Checklist
    2. Auditor Checklist
3. Scheduling
4. Materials/Equipment Requirements

Documents and Forms

- Pre-Audit Questionnaire
- Audit Checklist
- Findings Report
- Observations Report
- Letter

Roles and Responsibilities of Auditors

1. Auditor shall be objective in their findings and observations.
2. Utilize written objective quality evidence.

   (Guidance provided in QA Checklist)
3. Complete audit report in a timely manner.

   (It is preferable to leave the Auditee with a report and a letter or scheduled time to complete the audit)

NOTE: Auditor shall strive to be helpful and provide constructive guidance.

Roles and Responsibilities of Auditors

NOTE:

Auditees *not located in Virginia* must provide to the Auditor their QMS Manual with evidence of the seventeen critical items, be prepared for a follow-up teleconference and submit any additional supporting documentation requested by the Auditor digitally.

Roles and Responsibilities of Auditee

1. Auditee shall be prepared for audit and have documentation legible, identifiable and retrievable.
2. Auditee is responsible for responding to Findings in a timely manner. (60-days)

1. Preparation Checklists

1. Auditee Checklist

- Review Documentation Requirements
- Plan for a 4 hour time block when your audit team will be available for the auditor. Plan for management availability.
- Ensure the auditor will have on-line access to the QA website at www.virginiashiprepair.org and printer capability where possible
- Ensure you cleared the auditor for security access with your facility and has the proper PPE requirements

1. Preparation Checklists

1. Auditor Checklist

- Review Past Audit, if available, prior to audit
- Plan for a 4 hour time block
- Ensure you will have on-line access to the QA website at www.virginiashiprepair.org at the site and printing capability where possible
- Ensure you are cleared for security access with the host facility and have the proper PPE requirements

Communication with QA Committee Leadership

Resolving Issues

- QA Committee Chairman

Comments/Improvements

- Help Ticket on the QA website or
- Contact the QA Committee Chairman

Starting an Audit

1. 90-days before their audit is DUE, Auditees will be sent a link to complete their Pre-Audit Questionnaire.

2. Once they Submit the completed form, an email will go to the Point of Contact at their assigned Auditor Company with a link to assign the specific Auditor who will handle the audit.

3. The assigned Auditor will receive an email with a link to view the Pre-Audit Questionnaire and contact information for the Auditee to schedule the audit session.

Companies who have a Previous VSRA Audit

- Auditor and Auditee should review the previous audit
- Auditee should have RESOLVED Minor Findings from previous audit. If any are not resolved they should be marked as Major.

AUDITEES!!!
Key Notes Regarding Auditee Follow-up: Findings Report and Post Audit

SATISFACTORY with no Findings:

You will receive your letter at the end of the Audit. The Audit will be closed to amendments and only viewable by the Audited Company until the next Audit is due, at which time your Renewing Auditor will be able to view the previous Audit.

AUDITEES!!!
Key Notes Regarding Auditee Follow-up: Findings Report and Post Audit

SATISFACTORY with Minor Findings: You will receive your letter at the end of the Audit. The Audit will remain open for updates to the Auditee and the Auditor. The Auditee can update information in the Findings report and Submit it to the Auditor to be Resolved. Once All Findings are Resolved, the Audit will be closed to amendments and only viewable by the Audited Company until the next Audit is due, at which time your Renewing Auditor will be able to view the previous Audit.

AUDITEES!!!
Key Notes Regarding Auditee Follow-up: Findings Report and Post Audit

UNSATISFACTORY with Major and/or Minor Findings: You will NOT receive your letter at the end of the Audit. The Audit will remain open to the Auditee and the Auditor. The AUDITOR will complete the “Identify Problem” on every Finding. It is then UP TO THE AUDITEE to complete the Corrective Action and request the Auditor to resolve those items.

The Auditee must resolve ENOUGH of the Findings (no more than Four Minors in a Section and no Majors) and Submit it to the Auditor to be Resolved. When ENOUGH have been Resolved, the Auditor will be able to generate the letter.

AUDITEES!!!
Key Notes Regarding Auditee Follow-up: Findings Report and Post Audit

UNSATISFACTORY CHANGED TO SATISFACTORY with NO or Minor Findings: When ENOUGH have been Resolved, the Auditor will be able to generate the letter. If there are still remaining Findings the Audit will remain open to update until all are Resolved. Once All Findings are Resolved, the Audit will be closed to amendments and only viewable by the Audited Company until the next Audit is due, at which time the Renewing Auditor will be able to view the previous Audit.

What is the Basis for the VSRA QA Audit Checklist?

- NAVSEA Standard Item 009-04, Quality Management System
- ISO 9001:2008, Quality Management System – requirements.

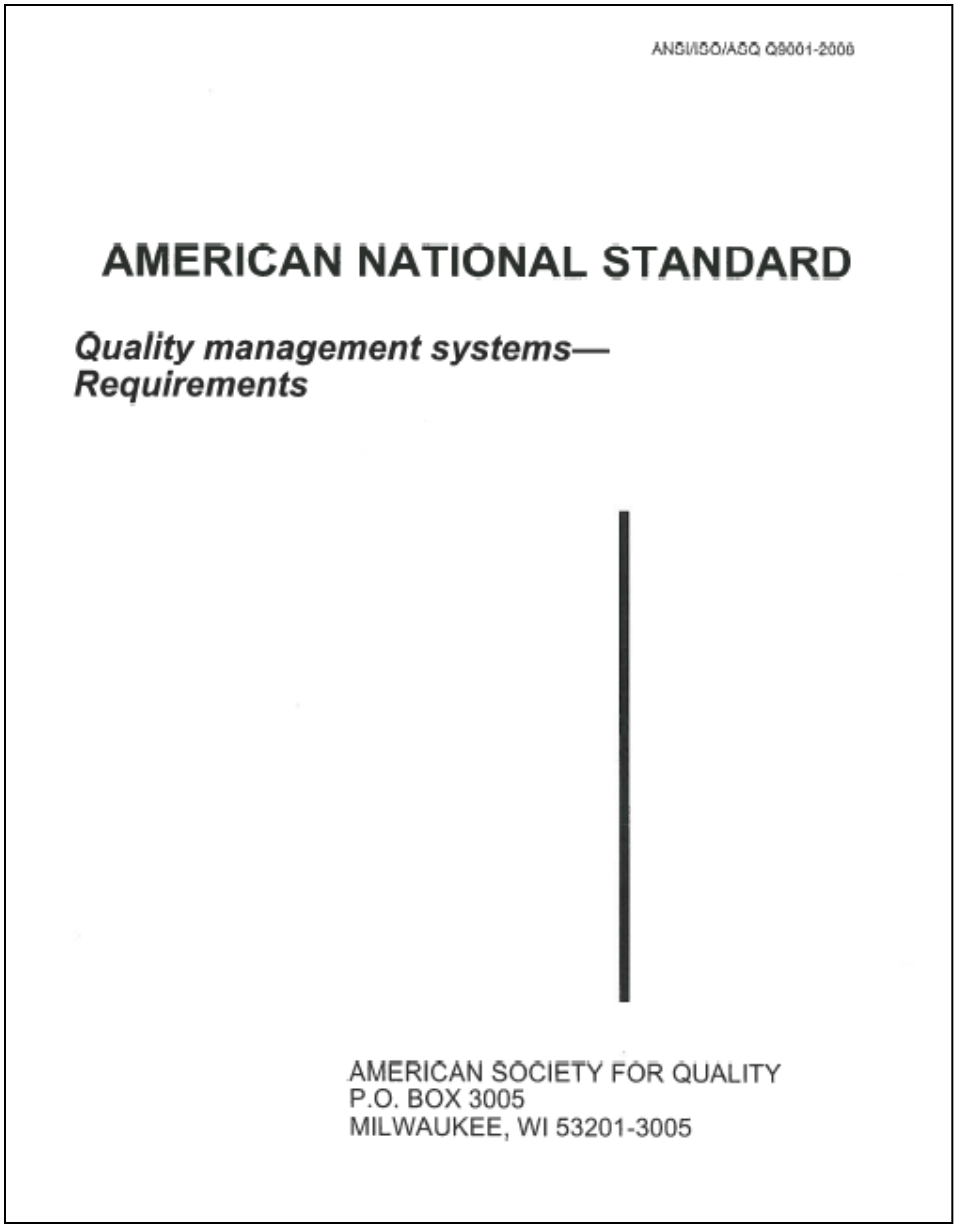
NAVSEA
STANDARD ITEM

FY-14
ITEM NO: 009-04
DATE: ***17 JAN 2013***
CATEGORY: I

1. SCOPE:
   1.1 Title: Quality Management System; provide

2. REFERENCES:
   2.1 Standard Items
   2.***2*** ANSI/ISO/ASQ Q9001-2008, Quality Management Systems - Requirements
   2.***3*** ANSI/NCSL Z540-3, Requirements for the Calibration of Measuring and Test Equipment
   2.***4*** ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories
   2.***5*** NAVSEA 04-4734, Navy and Marine Corps Calibration Laboratory Audit/Certification Manual
   2.6 SSPC QP1 Application, Instructions, and Program Rules

"The system shall, as a minimum, comply with the requirements of 2.2 and all additional contract requirements"



The QMS shall include…

- a quality manual
- a quality policy
- quality objectives

A documented procedure shall be established….

- Control of documents
- Control of records
- Internal audits
- Control of nonconforming product
- Corrective action
- Preventive action

ISO Clause Number	ISO Clause Name
0	INTRODUCTION
0.1	General
0.2	Process Approach
0.3	Relationship with ISO 9004
0.4	Compatibility with Other Management Systems
1	SCOPE
1.1	General
1.2	Application
2	NORMATIVE REFERENCES
3	TERMS AND DEFINITIONS
4	QUALITY MANAGEMENT SYSTEM
4.1	General Requirements
4.2	Documentation Requirements
4.2.1	General
4.2.2	Quality Manual
4.2.3	Control of Documents
4.2.4	Control of Records
5	MANAGEMENT RESPONSIBILITY
5.1	Management Commitment
5.2	Customer Focus
5.3	Quality Policy
5.4	Planning
5.4.1	Quality Objectives
5.4.2	Quality Management System Planning
5.5	Responsibility, Authority, and Communication
5.5.1	Responsibility and Authority
5.5.2	Management Representative
5.5.3	Internal Communications
5.6	Management Review
5.6.1	General
5.6.2	Review Input
5.6.3	Review Output
6	RESOURCE MANAGEMENT
6.1	Provision of Resources
6.2	Human Resources
6.2.1	General
6.2.2	Competence, Training, and Awareness
6.3	Infrastructure
6.4	Work Environment

ISO Clause Number	ISO Clause Name
7	PRODUCT REALIZATION
7.1	Planning of Product Realization
7.2	Customer-related Processes
7.2.1	Determination of Requirements Related to the Product
7.2.2	Review of Requirements Related to the Product
7.2.3	Customer Communication
7.3	Design and Development
7.3.1	Design and Development Planning
7.3.2	Design and Development Inputs
7.3.3	Design and Development Outputs
7.3.4	Design and Development Review
7.3.5	Design and Development Verification
7.3.6	Design and Development Validation
7.3.7	Design and Development Changes
7.4	Purchasing
7.4.1	Purchasing Process
7.4.2	Purchasing Information
7.4.3	Verification of Purchased Product
7.5	Production and Service Provision
7.5.1	Control of Production and Service Provision
7.5.2	Validation of Processes for Production and Service Provision
7.5.3	Product Identification and Traceability
7.5.4	Customer Property
7.5.5	Preservation of Product
7.6	Control of Monitoring and Measuring Equipment
8	MEASUREMENT, ANALYSIS AND IMPROVEMENT
8.1	General
8.2	Monitoring and Measurement
8.2.1	Customer Satisfaction
8.2.2	Internal Audits
8.2.3	Monitor and Measurement of Processes
8.2.4	Monitoring and Measurement of Product
8.3	Control of Nonconforming Product
8.4	Analysis of Data
8.5	Improvement
8.5.1	Continual Improvement
8.5.2	Corrective Actions
8.5.3	Preventive Actions

ISO 9001:2008 Table of Contents

Now, go back to NAVSEA 009-04

Include the following additional documented procedures:

- **Management Responsibility**
- **Customer Related Processes**
- **Purchasing**
- **Production and Service Provisions**
- **Monitoring and Measurement of Product**
- **Control of Monitoring and Measuring Devices**
- **Measurement, Analysis, and Improvement**

- Audits are assigned to an Auditing Company.
- Auditee will complete a Pre-Audit Interview Form prior to being assigned an Auditor.

Resume Interview

General Information	
Company Name: *	Virginia Ship Repair
QA Representative Contact Name: *	
QA Representative Contact Email: *	
QA Representative Contact Phone: *	
Check which of these apply to your Company:	☐ ABR Contractor ☐ AIT Contractor ☐ IDIQ Contractor ☐ MSR Contractor ☐ Ship Repairer Contractor
If any of the above apply, is your Company audited directly by NSSA?	○ Yes ○ No
Does, or will your company, perform work that is subject to the requirements under 009-04?	○ Yes ○ No
Is your Company facility located in Virginia?	○ Yes ○ No

- If the Auditee states they are audited by NSSA, a notification will go to VSRA Admin for review.
- If the Auditee states they do not perform work that is subject to 009-04, a notification will go to VSRA Admin for review.

Resume Interview

General Information	
Company Name: *	Virginia Ship Repair
QA Representative Contact Name: *	
QA Representative Contact Email: *	
QA Representative Contact Phone: *	
Check which of these apply to your Company:	☐ ABR Contractor ☐ AIT Contractor ☐ IDIQ Contractor ☐ MSR Contractor ☐ Ship Repairer Contractor
If any of the above apply, is your Company audited directly by NSSA?	○ Yes ○ No
Does, or will your company, perform work that is subject to the requirements under 009-04?	○ Yes ○ No
Is your Company facility located in Virginia?	○ Yes ○ No

If these are checked YES, then the Audit will add an Appendix for that function.

Have you successfully completed a VSRA Audit in the Past?		(•) Yes	( ) No
Have you successfully completed any of the following ship repair association audits in the past **12 Months?**	**Port of San Diego**	( ) Yes	( ) No
	Jacksonville	( ) Yes	( ) No
	Puget Sound	( ) Yes	( ) No
	Hawaii	( ) Yes	( ) No
Check which other Industry Audits you have successfully completed in the past **12 Months**:		☐ QP1	☐ AMMA (Weld/Braze/NDT) ☐ Z540 ☐

Do you currently perform, or will perform in the next 18 months any of the following:

- **Welding**
- **Brazing**
- **NDT related work**
- **Coatings**

If they HAVE completed an Audit before, the Auditor will request the Auditee to show their previous audit.

Have you successfully completed any of the following ship repair association audits in the past **12 Months?**

Port of San Diego	○ Yes	○ No
Jacksonville	○ Yes	○ No
Puget Sound	○ Yes	○ No
Hawaii	○ Yes	○ No

Check which other Industry Audits you have successfully completed in the past **12 Months**:

☐ QP1 ☐ AMMA (Weld/Braze/NDT) ☐ Z540 ☐

Do you currently perform, or will perform in the next 18 months any of the following:	**Welding**	○ Yes ○ No
	Brazing	○ Yes ○ No
	NDT related work	○ Yes ○ No
	Coatings	○ Yes ○ No
Have you successfully completed a VSRA Audit in the Past?		◉ Yes ○ No

These are information questions only.

Critical Items — Download Blank Audit Form

Item	Readily Available	Available but Incomplete	Do not have available
Quality Management System	☐	☐	☐
Quality Manual	☐	☐	☐
Quality Policy	☐	☐	☐
Quality Objectives	☐	☐	☐
Procedure for Control of Documents	☐	☐	☐
Procedure for Control of Records	☐	☐	☐
Procedure for Internal Audits	☐	☐	☐
Procedure for Control of Nonconforming Product	☐	☐	☐
Procedure for Corrective Action	☐	☐	☐
Procedure for Preventive Action	☐	☐	☐
Procedures for Management Responsibility	☐	☐	☐
Procedures for Customer Related Processes	☐	☐	☐
Procedures for Purchasing	☐	☐	☐
Procedures for Production and Service Provision	☐	☐	☐
Procedures for Monitoring and Measurement of Product	☐	☐	☐
Procedures for Control of Monitoring and Measuring Devices	☐	☐	☐
Procedures for Measurement, Analysis, and Improvement	☐	☐	☐

Save and Submit Later

Submit for Audit

Every CRITICAL Item must have a checked box in the GREEN Zone in order to have the Auditing company assign an Auditor.

You have a required critical item that is NOT readily available. You must have this on hand to start the audit.

This is the notice the Audited Company will receive if they don't meet all of the requirements.

In addition, they can Download a Blank copy of the Audit Form to help prepare.

Critical Items			
Item	Readily Available	Available but Incomplete	Do not have available

Pre-Audit Interview Form was successfully submitted.

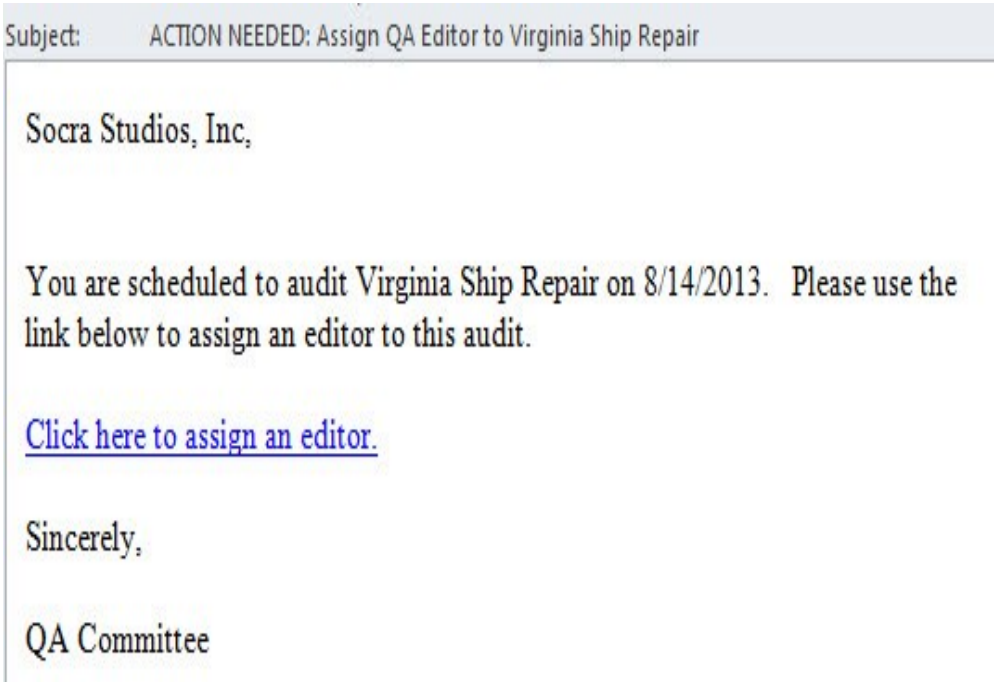
Audit Interview Form Submitted

Your audit interview form was successfully submitted!

You are currently scheduled to be audited by **Socra Studios, Inc** due **8/14/2013**. They have been notified to begin the audit.

Return to main page

When the Audited Company successfully submits their Interview form, the Auditing Company Primary Contact will receive an Email with a link for them to assign an Auditor



Subject: ACTION NEEDED: Assign QA Editor to Virginia Ship Repair

Socra Studios, Inc,

You are scheduled to audit Virginia Ship Repair on 8/14/2013. Please use the link below to assign an editor to this audit.

Click here to assign an editor.

Sincerely,

QA Committee

Interview Form

http://www.virginiashiprepair.org/qa/AuditInterviewEdit.aspx?scheduleId=473

Q & A