

AUDIT PROGRAM

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Management Systems Analysis, Inc. P.O. Box 136, Royersford, PA 19468 610-409-0168 jhighl@aol.com

Approved: Vames (Linkleus)

1.0 Objective

To describe the procedures and methods used by Management Systems Analysis Inc. (MSA) for conducting supplier audits and surveys. This Procedure also establishes the requirements for the qualification of auditors (Lead Auditors) who organize and directs audits, reports, audit findings and evaluates corrective action.

2.0 Scope

The provisions in this procedure apply to the performance of supplier audits and surveys by MSA personnel to verify implementation of supplier's quality programs and compliance to the requirements of the customer's purchase order. This procedure does not supersede any procedure checklist or method required by the client. In the event of a conflict the client's requirements shall take precedence over any MSA requirements.

3.0 General

MSA performs audit and survey activities in accordance with Quality Procedures, Checklists and Purchase Order requirements as specified by the client.

MSA does not procure material, equipment, or services for their own use; consequently the activities described relate exclusively to audits and surveys we conduct on behalf of our client.

All clients specified procedures and/or checklists shall take precedence over MSA's procedures and/or checklists.

- 3.4 This document was developed using the guidance of ISO 10011 and NQA-1.
- 3.5 All discrepancies or condition that may adversely affect the operation of an NRC licensed facility (per 10CFR21) will be reported to the client within 2 days of discovery or alternatively to the individual listed below when the client cannot be reached.

James Highlands, President MSA, Inc. 610-409-0168

4.0 Audit/Survey Procedure

Upon receipt of an audit/survey request or order MSA shall review the request to assure the inclusions of all required information and/or requirements.

- 4.2 Upon acceptance of an order MSA shall complete an Assignment Plan, including the customer name, location, name and location of the supplier to be audited/surveyed, supplier contact, supplier's telephone number, type of activity to be performed, audit/survey scope (i.e. customer purchase order requirements, standards, O.A. Program & commodity), the activity to be audited/surveyed, date the activity is to commence at the supplier's facility, and the assigned MSA Auditor.
- 4.3 An MSA Auditor shall be assigned to perform the audit/survey, and transmit the assignment plan.
- 4.4 The supplier to be audited/surveyed shall be contacted by the Auditor to confirm the date of the audit/survey; and to review the scope, purpose, and procedures for conducting the audit/survey.
- 4.5 Prior to visiting the supplier to be audited/surveyed, the Audit Team Leader shall review the assignment plan to ascertain that the scope and purpose of the assignment is understood in terms of the commodity and applicable quality requirements.

4.6 Pre-Survey Conference

A brief Pre-audit conference shall be conducted with the supplier representative. The purpose of this conference shall be to confirm the scope of the audit, introduce auditor(s), meet escorts, discuss audit sequence and plans or the post-audit conference and to establish channels of communication.

4.7 Investigation

Established checklists shall be used to ensure depth and continuity of investigation. The audit checklist is intended for use as a guide and shall not restrict the investigation when findings raise questions that are not specifically included in the checklist.

Objective evidence shall be examined during the course of the investigation and used as a basis to determine compliance with quality program requirements.

All elements of the quality program shall be investigated to the depth necessary to determine compliance with established requirements and effective implemented.

When a nonconformance or quality program deficiency is found it shall be documented by the auditor; further investigation shall the responsibility of the supplier to identify the cause and effect and to determine the extent of corrective action required.

4.8 Post-Audit Conference

At the conclusion of the investigation, a post-audit conference shall be held with the supplier to present the results of the audit. Any deficiencies/audit findings discovered during the course of the investigation shall be discussed with the suppliers' representative and any misunderstandings about the audit results clarified.

- 4.9 Deficiencies disclosed during the course of the audit shall be documented on an Audit Finding Report. As a minimum the report will identify the requirement violated and describe the deficiency or violation observed.
- 4.10 The Auditor shall advise the supplier of all Audit Findings prior to departing the supplier's facility.
- Upon completion of the audit, the Auditor will advise the client of the results and complete a Report of Audit, which shall be transmitted, along with the completed checklist, and any Audit Finding Reports to the client. The audit report shall contain the following:
 - -The date the audit was performed.
 - -The supplier name and address.
 - -A description of the audit scope.
 - -Identification of the auditor(s).
 - -Persons contacted during the survey.
 - -A description of each finding in sufficient detail to assure that corrective action can be carried out by the supplier.
- 4.12 MSA shall review the report for completeness, accuracy and, legibility; and transmit the completed package to the client.

4.13 Audit Findings

All Audit Finding Reports are transmitted to the client for review, and to request corrective action of the supplier, including any required follow-up activities. Alternatively, at the clients' direction, MSA will contact the supplier to solicit documented corrective action and perform an administrative review or follow-up audit to close the finding.

5.0 Qualifications of Auditors (Lead Auditors)

This Section delineates the qualifications requirements for Auditor (Lead Auditors) at MSA.

It shall be the responsibility of MSA to implement the applicable requirements of this standard, including the training, evaluation of experience, qualification, certification of Auditors (Lead Auditors), and the transmittal of appropriate records to the client for their review. It shall be the responsibility of the client to review said certification to determine their suitability and compliance with the provisions of their quality program.

Qualification of Auditors: An individual shall meet the requirements of paragraphs 5.3.1 through 2.3.5 prior to being designated an Auditor.

- 5.1 Education and Experience. The prospective Auditor shall have verified evidence that a minimum of ten (10) credits under the following scoring system have been accumulated.
- 5.1.1 Education (4 credits maximum). Associate degree from an accredited institution score one(1) credit or if the degree is an engineering, physical sciences, mathematics, or quality assurance, score two(2) credits or, a bachelor degree from an accredited institution score two(2) credits or if the degree is in engineering, physical sciences, mathematics, or quality assurance, score three(3) credits; in addition score one (1) credit for a master degree in engineering, physical sciences, business management, or quality assurance from an accredited institution
- 5.1.2 Experience (9 points maximum). Technical experience in engineering, manufacturing, construction, operation, or maintenance, score one(1) credit for each full year with a maximum of five (5) credits for this aspect of experience. If two(2) or more years of this experience have been in the nuclear field, score one(1) additional credit, or, if two(2) or more years of this experience have been in quality

assurance, score two (2) additional credits, or, if two(2) or more years of this experience have been in auditing, score three (3) additional credits, or, if two(2) or more years of this experience have been in nuclear quality assurance, score three (3) additional credits, or, if two(2) or more years of experience have been in nuclear quality assurance auditing, score four (4) additional credits.

- 5.1.3 Other Credentials of Professional Competence (2 credits maximum). Certification of competency in engineering, science, or quality assurance specialties issued and approved by a State Agency. or National Professional or Technical Society, score two(2) credits.
- Rights of Management (2 points maximum). MSA may grant up to two(2) credits for other performance factors applicable to auditing which may not be explicitly called out in this standard. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, QA training courses or evidence of prior certification.
- 5.2 Communication Skill. The prospective Auditors shall have the capability to communicate effectively, both written and oral. These skills shall be attested to in writing by MSA.
- 5.3 Training. Prospective Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Auditor.
- 5.3.1 Knowledge and understanding of applicable codes, standards, regulations, regulatory guides.
- 5.3.2 General structure of quality assurance programs as a whole and applicable elements such as organization; design control; procurement document control; instructions, procedures and drawings; document control; control of purchased material equipment and services; identification and control of materials, parts and components; control of special processes; inspection; test control; control of measuring and test equipment; handling, storage and shipping; inspection, test, and operating status; nonconforming materials, parts, or components; corrective action; quality assurance records; audits; and quality information feedback.

- 5.3.3 Auditing techniques of examining, questioning evaluating and reporting, methods of identifying and following up on corrective action items, and closing out audit findings.
- 5.3.4 Audit planning in the quality-related functions for the following activities; design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, nondestructive examination, maintenance, repair and operation.
- 5.3.5 On-the-job training to include the elements of audit activity as described in applicable auditing procedures.
- Audit Participation. The prospective Auditors shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to his qualification.
- 5..5 Examination. The prospective Auditor shall pass a written examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified in paragraph 5.3.3.
- 5.6 Maintenance of Qualification

General: The maintenance of proficiency established in this Section shall apply to Auditors only.

- Maintenance of Proficiency: Auditors shall maintain their proficiency ∃ through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance programs and program auditing; participation in training programs. Based on management annual assessment, management may extend the qualification, require retraining, or require requalification. These evaluations shall be documented.
- Requalification: Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include retraining in accordance with paragraph 5.3.3, reexamination in accordance with paragraph 5.3.5, and participation as an Auditor in at least one quality assurance audit.

Management Systems Analysis, Inc.

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Audit/Survey Procedure

- 6.0 Records
- 6.1 Certification of Qualification: Each Auditor shall be qualified to lead audits.

This certification shall, as a minimum, document the following:

- (a) MSA's name
- (b) Auditor's name
- (c) Date of certification or recertification
- (d) Basis for qualification
- (e) Signature of MSA's designated representative who is responsible for such certification.
- 6.2 Records for each Auditor shall be maintained and updated annually. Updated records shall be forwarded to the client annually for their review and acceptance of the auditor's qualification records.
- Records of completed audits are forwarded to the client for maintenance as quality records within the scope of their quality program.