GUIDE FOR QUALITY SYSTEM REGISTRATION

ISO 9000

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TABLE OF CONTENTS

INTRODUCTION

AEA Quality Registrars, Inc. is incorporated in the State of New York with its principal office located at 11 Marshall Road, Suite 1-S, Wappingers Falls, New York 12590, USA. It provides internationally recognized third party certification and registration of client quality management systems to the ISO 9000 standards.

AEA operates in accordance with ***the new standard ISO 17021, which replaces ISO/IEC Guide 62, EN 45012 and ISO/IEC Guide 66***, European standards for registrars and ISO 19011, International standard for auditing, auditors and audit program management.

AEA's Certification Services are accessible to all Organizations. There are no undue financial conditions. The access is not denied based on Client's affiliation, and/or linkage to other services that may be offered by AEA. AEA does not speed up or delay applications without valid reason. Certification of a Management System is not denied for matters that are irrelevant and/or not covered by the applicable Quality Standards.

AEA Auditors who have either financial interest in the client organization or have/had consultancy or internal auditing relationship with the client organization within the last two years are prohibited from conducting certification assessments.

AEA's Certification personnel including management are required not to have been involved in any consultancy or internal auditing activities within the last two years with the Client or a related company where such a relationship may compromise their impartiality.

Any AEA's part-time or permanent personnel must not have other employment, which may be perceived as to compromise their impartiality.

To date the AEA's Staff has completed over 100 quality management system assessments.

This guide covers the scope of AEA's assessment, certification and registration services. Throughout this guide AEA's client is referred to as the "Organization."

ISO 9000 STANDARDS

Internationally accepted requirements for quality management are defined in the ISO 9000 series of three standards: ISO 9000, ISO 9001 and ISO 9004. ISO 9000 provides the "Fundamentals and Vocabulary", ISO 9001 provides requirements for a Quality Management System (QMS), and ISO 9004 provides guidelines for top management to continually improve the performance of its Organization. Almost every country in the world has adopted these documents so all requirements are identical. ANSI/ASQ 9000 is the American standard, BS5750 is the British standard and in Europe the standard is designated as EN29000. ISO 9000 series are the international standard.

An Organization seeking registration must select ISO 9001 standard with acceptable exclusions, as appropriate to its activities but limited to the requirements within the Clause 7.0. A requirement within the Clause 7.0 can be considered for exclusion only if it cannot be applied due to the nature of an organization and its products. Such exclusions must not affect the Organization's ability, or

responsibility, to provide product or service that meets customer and applicable regulatory requirements. Where exclusions are made for requirements of the standard other than the clause 7.0, claims of conformity to the ISO 9001 standard are not acceptable. The details are provided in the standard itself. AEA will be pleased to help make the right choice.

ISO 9001 registration is not simply a one-time program: it's an ongoing process and is the basis for continual improvement. The key concepts are:

Document
This means writing down how an Organization conducts its business at each step of the entire operation that affects the quality of the product or service in accordance with the requirements of the ISO 9001standard.

Follow the Documentation
Everything that employees do within an Organization must be carried out in accordance with the written documentation.

Demonstrate
The Organization should be able to demonstrate, through documented objective evidence, to a third party auditor that its quality management system is implemented effectively and meets the requirements of the quality standard.

Verify
The Organization must conduct thorough internal audits of its quality management system, at least annually to ensure continuing effectiveness despite changes in business conditions.

CERTIFICATION AND REGISTRATION

Certification and registration to the ISO 9001 standard provides market confidence that the Organization is capable of systematically meeting the requirements set forth in the standard for any product or service supplied within the scope specified on the certificate.

Registration is provided to an Organization by a ***CAB (Conformity Assessment Body - who provides audit and certification of management systems)***, such as AEA, after the Organization's quality management system has been assessed and certified as meeting the requirements of the ISO 9001 standard.

Subsequent to registration, the Organization receives a certificate displaying the appropriate certification marks and is permitted to use this per the rules outlined in the service contract. The Organization is included in a list of certified Organizations with an outline of the scope of the certification. This list is published periodically by AEA and other global publishing organizations.

ACCREDITATION

Accreditation is a status awarded to ***CABs (Conformity Assessment Bodies - who provide audit and certification of management systems)*** by a national authority called Accreditation Body or Board. It indicates that the ***CAB*** has been audited by the ***accreditation body*** to determine its ability and competency to audit against the requirements of the ISO 9001 standard for a specific activity.

Currently AEA is accredited by RvA (Raad Voor Accreditatie) the Dutch Accreditation Council.

It is AEA's policy to apply for accreditation in every new business area in which it intends to serve.

Currently, each nation of the world has the right to establish its own Accreditation Body under the auspicious of the IAF (International Accreditation Forum) who regulates the day–to–day accreditation process for the ISO (International Standardization Organization). The IAF has established rules and regulations under which it harmonizes the accreditation bodies thus making accreditation by any accreditation body universally accepted in the world. With the existence of this uniform system for international accreditation, AEA has the authority to conduct its certification business in all countries where it chooses to operate, directly or through Memorandum of Understanding (MOU) with other certification bodies.

REGISTRATION PROCESS

Application for Registration
The first step in AEA's process requires the Organization to complete the application form or "Client company profile" form. This information enables AEA to understand the nature of the Organization's business, the activities that support it and to establish a match with AEA's expertise.

Quotation and Contract
When ***the Director of Sales*** receives a completed application from an Organization, ***it reviews Client's desired Scope of Certification Vs their Core Processes and against AEA's EA/IAF Accredited Codes. If any discrepancy is noted, informs the Director of Operations of the discrepancy for resolution / planning.*** Then it sends a quotation with a contract to the Organization. If the Organization wishes to proceed with the registration, receipt of the signed contract by AEA starts the process.

Scheduling of Dates
AEA's Director of Operations contacts the Organization and arranges mutually agreeable dates for ***(Stage–1, per the ISO/IEC 17021 Standard, clause 9.2.3.1) which includes documentation review, preparedness status for Stage-2, scope of the management system, status of the internal audits & management reviews and gaining sufficient understanding for the planning of stage-2 audit.*** The Stage-1 assessment is generally scheduled four to six weeks prior to Stage-2 audit to enable the Organization to correct any nonconformity that may be identified. The Director of Operations also assigns an assessment team to complete the assignment.

Documentation Review
The documentation review is conducted by a member of the assigned assessment team and may take place partially at the Organization's premises. During the review, the assessor ensures that the Organization's documented quality management system meets the requirements of the ISO 9001 standard. Any nonconformity must be corrected before certification/re-certification assessment can commence.

Assessment

The assigned assessment team carries out the assessment ***(Stage-2 per the ISO/IEC 17021 Standard, clause 9.2.3.2)*** and in accordance with AEA's rules and procedures. The assessment starts with an opening meeting and ends with a closing meeting with the Organization's management. All nonconformities identified during the assessment are required to be acknowledged by the Organization. The lead assessor informs the Organization's management regarding the team's recommendation along with the required corrective actions during the closing meeting.

Reporting
The lead assessor submits the assessment report with the team's recommendation to the Director of Operations. The Director of Operations reviews the report for completeness and submits it to the Director of Certification. The Director of Certification acts on the recommendation of the assessment team and informs the Organization accordingly. In the event the Organization does not meet the requirements for certification, the Director of Certification decides on the follow up activities, including special surveillance visits with the Organization.

Registration
AEA issues a certificate of registration on the completion of a satisfactory assessment. This assumes that the nonconformities identified during the assessment have been satisfactorily resolved. The certificate will detail the Organization's scope of certification. The certificate is valid for three years subject to satisfactory maintenance of the Organization's quality management system. The certificate remains the property of AEA.

Maintenance Surveillance
Once an Organization's quality management system has been certified and registered, it is essential to maintain the system's operation to the ISO 9001 standard requirements. To ensure this, AEA conducts surveillance assessments at ***agreed upon intervals (No more than 12 months intervals)*** in such a way that all sections of the Organization's quality system are examined at least once during the three-year registration period.

Special Surveillance
If it becomes necessary, AEA will conduct special surveillance visits in the course of maintaining the registration. Circumstances may include an Organization wishing to extend the scope of certification, in response to an incident or a significant change in the Organization's quality management system.

Re-assessment
AEA practices ***according to IAF Guide lines audit man-days, which is 2/3 of the initial certification man-days. The re-assessment may require stage-1 auditing (At least the documentation review) based on the level and significance of the changes in the management system.*** However, a new certificate is issued at the end of three-year certification period. The extent of the re-assessment depends on the Organization's demonstrated ability to maintain its system as determined during the surveillance visits. ***Regardless of the surveillance audit intervals frequency, re-certification requires documentation review at the end of three-year certification period.*** A successful review and audit, results in the extension of the certification for an additional three-year period.

MAJOR AND MINOR NONCONFORMITIES

Definitions of major and minor nonconformities and their relationship with each other are provided in AEA's procedure # OP 810-11, and also presented by the Audit team during the opening meeting with the organization. A copy of the procedure is available upon request.

PRE-ASSESSMENT

While developing their quality management system for certification, the Organizations often need an outside opinion to reassure them that they are proceeding in the right direction. To address this need, AEA offers an optional pre-assessment service. However, this service does not influence in any way the conduct of assessment for certification. Pre-assessments are designed to help provide Organizations with a clear understanding of interpretations of the ISO 9001 standard, details of quality system deficiencies and an evaluation of their progress towards ISO 9001 certification.

Pre-assessment is conducted as an informal assessment. The findings are presented to the organization's management at the end of the assessment followed by a detailed report of the system's deficiencies. The results help plan the activities leading to the certification assessment in a realistic manner.

Pre-assessment also provides an opportunity to develop an effective working relationship between the Organization and the assessment team at an early stage. The resulting partnership could significantly reduce the anxiety often associated with the certification process.

USE OF CERTIFICATE AND CERTIFICATION MARKS

An Organization, whose quality management system has been certified, will be issued a certificate of registration and soft copy of the certification marks together with relevant instructions covering the reproduction and use of the certificate and certification marks, ***which AEA is obliged to control in compliance with the ISO/IEC 17021 Standard.***

The Organization is entitled to display its certificate at its place of work or in any promotional or advertising literature. The Organization also has the right to use certification marks on letterheads and brochures, etc. for related publicity activity ***(Per the ISO/IEC 17030 Standard requirements)***. Under no conditions may the marks be affixed to a product or used in a way that might suggest product certification.

SUSPENSION, OR WITHDRAWAL OF CERTIFICATION

The certificate of registration is the property of AEA. For a valid reason, AEA reserves the right to suspend, withdraw or cancel the certificate at any time during the three-year registration period.

Certificate of registration may be suspended, or withdrawn per AEA procedure OP 810-09. Generally, suspension, withdrawal or cancellation is considered in the following instances:

- If an Organization requests withdrawal of the certificate.
- If an Organization has not paid fees after the due process for collection.

- If an Organization fails to take corrective action as directed.
- If an Organization refuses or fails to schedule required maintenance surveillance assessment, special surveillance assessment or re-assessment.
- If an Organization ceases to exist as a legal entity in its form as certified.
- If an Organization misuses the certificate or the certification marks and refuses to take corrective action to cease the misuse.

AEA reserves the right to publish, in whatever way it feels fit, the suspension, withdrawal or cancellation of the Organization's certificate of registration.

DISPUTES, *EXPRESSION OF DISSATISFACTION*, COMPLAINTS, AND APPEALS

A Client or any other concerned party may dispute the decisions of AEA in regard to Certification matters *or may express expression of dissatisfaction*. This request must be made in writing to the President. Disputes *or expression of dissatisfaction* are resolved objectively and on timely basis by the Dispute Review Board. If the party finds the resolution to be unsatisfactory, it has an option available to file an appeal with the President, in writing. An independent Arbitration Board established by the Board of Directors handles such appeals, which renders its decision on the issue(s). If the aggrieved party does not accept the decision of the Arbitration Board, it has the right to a legal recourse. Disputes and subsequent appeals are handled per the Corporate Operating Procedure # OP 815-01.

AEA maintains records of disputes, appeals & their resolutions for a reasonable period.

If an Organization or a third party wishes to lodge a dispute, complaint or appeal the decision of AEA in regard to the following:

- **Rejection of an application for registration.**
- **Failure to recommend certification.**
- **Suspension, withdrawal or cancellation of a registered certificate.**
- **An appeal by a third party against a decision to grant certification.**
- **Any other matter of contention.**

AEA has a procedure, OP 815-01, for affording the appeal process.

DOCUMENTS AVAILABLE TO PUBLIC

An uncontrolled copy of the latest revision of the following procedures will be provided upon request. Holders of uncontrolled copies of documents do not receive future updates of the documents.

- OP 815-01 Resolution of disputes and appeals.
- OP 817-01 Use of Certificate and Certification Mark.

- OP 814-01 Publication of Certificated suppliers.
- Op 808-02 Amendments to the ISO 9000 Certification System.
- OP 810-04 Quality System Surveillance activities and re-assessments.
- OP 810-09 Suspension / withdrawal of Certificate.
- OP 810-11 Evaluation of nonconformities.

CONFIDENTIALITY

Any Organization's information received by AEA or its agents, during the course of certification, will be treated in strict confidence and will not be divulged to a third party without prior written consent of the Organization, except as required by the Laws of the land or other relevant accreditation bodies.

COST OF CERTIFICATION

Each Organization's management system is unique as it reflects its management style and activities. Thus, the actual cost for certification and subsequent maintenance may vary for individual Organizations. The information provided herein is intended to give a broad outline of costs.

When an Organization completes and returns the application form, AEA prepares a specific quotation. AEA charges a one-time or yearly, non-refundable application fee, which covers administration costs throughout the three-year term of the certification process. All other costs are based on a standard day rate and are charged on per man-day. This rate is used to calculate the costs of all visits to the Organization's premises including optional pre-assessment, documentation review, initial assessment and any other visits required to verify corrective actions before the certificate is issued. This rate is also used for subsequent visits during the three-year certification period. In addition to a day rate charge per visit, AEA charges travel and related expenses at cost. AEA also has a policy to provide fixed cost quotes, if so requested, for its regular services of documentation review, initial assessment, regular surveillance audits, and re-certification. Any special visits will be invoiced separately based on the man-day rate plus travel expenses. Time spent traveling and off site report preparation is included in the total cost of each visit. AEA takes pride in controlling its costs and passing these savings on to its Clients. Its day rate normally falls at the low end of the prevailing industry rate scale.

AEA's cost structure is simple and Client friendly. The application fee is charged when the contract is signed. Thereafter, invoices are sent following each service activity. AEA issues the certificate once all invoices have been paid.

- ***Auditors who have either financial interest in the client organization or have/had consultancy or internal auditing relationship with the client organization within the last two years are prohibited from conducting certification assessments.***

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