Perry Johnson Registrars, Inc.

Summary of Quality Registration Procedure

PJR offers registration services to companies, which seek independent validation of their quality systems. Registration to the international quality standard ISO 9001:2000, the automotive industry's QS-9000: 1998 standard, AS9100, ISO 13485, or any other Quality Management System is a detailed and rigorous process. This procedure outlines the registration process from start to finish, detailing a step-by-step approach from initial application to continuing surveillance after registration has been achieved. This document is a summary of PJR controlled procedure PRO-1: Quality Registration Procedure.

Amendment Record

Date	Details	Rev Level
9/19/03	Change "environmental management" to quality management system" on page 10	2.8
9/19/03	Add amendment page. On page 11, add "Any organization being audited for the purpose of being issued a certificate containing any Accreditation Body's Seal must permit PJR's audit team to be accompanied by any Accreditation Body's accreditation auditors for the purpose of witnessing PJR's audit team."	2.9
9/30/03	On page 5, add "Audit plan submission should occur no less than two weeks prior to the audit, under normal conditions."	3.0
10/3/03	On page 1, add references to ISO 13485.	3.0
10/3/03	On page 3, add "For registration to ISO 13485, the organization completes F-1med and transmits to PJR. In no way may the account executive take the information by phone. Prior to the issuance of any quote, PJR must receive the organization's permits and licensing agreements issued by the applicable government. This information must detail the classification and purpose of the medical device(s) being manufactured."	3.0
11/3/03	On page 2, change to "PM", page 4 add "KBA, KBA", page 5 add "applicable," add "For ISO/TS 16949, no more than one (1) pre-assessment may take place", add "one", delete "Audit plan submission should occur no less than two weeks prior to the audit, under normal conditions", delete "also", page 7 delete "International Manager/Audit Initiatives", replace "(APM) with (PM)", page 8 delete "International Manager/Audit Initiatives", replace "(APM) with (PM)", change font, replace "IM/AI (APM) with (PM), page 10 replace "APM with PM", page 12 add "KBA".	3.1
01/15/04	On Page 2, 1st paragraph, delete "quality manual," replace with "manual." On page 3 replace "agreements" with "approvals" On page 5 delete "audit plan submission should occur no less than two weeks…" On Page 10 add "Guidance on."	3.2
02/09/04	New wording from ISO 9001:2000. Change all words that read "supplier" to the word "organization".	3.3
04/20/04	Corrections on page 1. Added, "AS9100" and "any other Quality Management System" Page 2, Deleted entire sentence below title, "Amendment Record". Page 13, Added EA No., 34 with Description "Engineering Services". Page 14, Added EA No., 13 with Description "Pharmaceuticals", 30 with Description "Hotels and Restaurants", and 37 "Education". Page 16, Added EA No 38 with Description Health and Social Work.	3.4
05/27/04	Page16, Added Scope of Accreditation for Italy	3.5
06/03/04	Page 10, Added EMS/QMS combined audit information.	3.6
07/16/04	Page 11, last bulleted point under Combined Audits was added.	3.7
07/29/04	Page 10 added, "Combined audits may be registrations, surveillances, or re-certification audits."	3.8
08/20/04	Page 14, Delete scope of Accreditation JAB because it is suspended as of 08/13/04.	3.9
10/05/04	Page 14, Add scope of Accreditation JAB back, it was re-instated 9/27 Page 6, Clarification of Major definition under Resolution of Corrective Action(s).	4.0
11/15/04	Page 9, added "Upon application … three year period." Page 10, added "All recertification … the scheduled audit."	4.1
1/9/06	Throughout document, corrected "ISO 9000 (series)" to "ISO 9001: 2000," "QS" and "QS-9000" to "QS-9000: 1998," "TE" to TE	4.2

Date	Details	Rev Level
	Supplement," "ANSI-RAB" to "ANSI-ASQ," "RAB" to "ANAB," and "non-conformance(s)" to "nonconformity(ies)." Added "NACE/EA" to "SIC Code." Deleted "VDA" and all associated references. Deleted references to "AS9000." Resolution of Corrective Action(s) (ISO 9001: 2000), added "c) An Opportunity … for OFIs)" and "d) An Observation … for observations)" and replaced "Corrective Actions must … Closing Meeting" with "Clients must submit … Supplement audit." Registration, 2nd paragraph, replaced underlined "Audit was made" with "conducted." 3rd paragraph, added underlined "(3 months' data)." Maintenance of Registration and Surveillance Audits, 1st a), added parentheses and deleted "Upon application to …three-year period." Combined EMS and QMS Audits, deleted section addressing Split/Combined Audits. Witness Assessment, replaced underlined "Accreditation Body's accreditation" with "or PJR's." "Appeals" section corrected to "Dispute and Appeals," added underlined (x2) to correct reference "Dispute/Appeal" and corrected "a" to "an" in both a) and d). Outline of Requirements, i) corrected to match text of Witness Assessment section. Scopes of Accreditation: UKAS, deleted "(full)" from 7, 8, 12, 13, 14, 17 (corrected from 15), 18, 19, and 29, deleted "(limited)" from 28 and 35, and added 33 and 34. INMETRO, added EA 34 and underlined "every SIC/NACE code." SINCERT, added EA 16 and 28.	
04/28/06	Added "EA 03" under SINCERT scope of accreditation	4.3

Summary

This document describes the procedures to be followed for the achievement of registration of an Organization's QMS. It describes actions required by both PJR and the Organization to complete the registration process.

This document also describes the procedure to be followed for a Organization requesting to be certified by PJR during a registration assessment period commenced by a registration body other than PJR.

To achieve and maintain registration, the Organization must meet the requirements of this and other supporting PJR documents and must subsequently maintain its QMS system in satisfactory operation.

An Organization registered under this Scheme receives a "Registration Certificate of Approval" of its QMS and is entitled to advertise and display the appropriate PJR Registration Mark.

The registration conferred by PJR covers only the products/services under the control of the Organization as described in the scope and enumerated on the Certificate. The Organization is obligated to make clear to Customers which products/services are covered by the Registration Certificate of approval.

All PJR employees are required to observe this procedure, which is under the direct control of the President of PJR.

Request for Registration

The Organization initiates the Registration Process via a written or verbal request for information. In response, PJR provides Organization with the following:

Client Profile / Questionnaire (F-1)

The Organization completes PJR standard form F-1 (or PJR takes information by phone) to provide PJR with the initial information required to commence the registration process. This document elicits from the Organization the following details, among others:

a) Contact name (address, etc.)
b) Description of business and SIC/NACE/EA code(s)
c) Description of premises of facility, number of employees, number of work shifts
d) Status of existing quality system

For registration to ISO 13485, the organization completes F-1med and transmits to PJR. In no way may the account executive take the information by phone. Prior to the issuance of any quote, PJR must receive the organization's permits and licensing approvals issued by the applicable government. This information must detail the classification and purpose of the medical device(s) being manufactured.

On the basis of the information furnished by Organization, PJR provides a quotation to cover the cost of the registration and subsequent surveillance visits. The required number of audit man-days is determined using the appropriate audit day Grid as timetable guidelines. The quotation can include the cost of any pre-assessment, but excludes follow-up visit(s) that may be recommended or required for the successful completion of the registration process. It also assumes the accuracy of the information provided by Organization, and is subject to change to cover additional work by PJR caused by inaccurate or incomplete information.

If the registration concerns the enrollment of a Organization with a current certificate as described above, the basis for the quotation may deviate from IAF minimum guidelines based on any or all of the following:

- the time elapsed since the actual registration audit, and/or last surveillance audit
- the details of prior nonconformities and status of corrective actions
- following the review of all system documentation by PJR Audit personnel.

In the event that there is a difference in understanding between PJR and the applicant, it must be resolved prior to the Registration Audit.

In the event that the client would like to be registered to an SIC/NACE/EA Code for which PJR is not approved (see

the last page of this document for a current list of accredited scopes), the sales representative needs to complete a scope extension application form (F-65) and return it to the Accreditation Manager immediately upon receipt of a deposit.

Should Organization wish to proceed with registration, PJR provides a copy of the appropriate F-3, the Registration Agreement. Organization then completes, signs, and returns a copy of F-3 bearing an original signature. The receipt by PJR of this document is taken as an instruction to proceed in accordance with F-3 (Registration Agreement) and associated procedures, and Organization is sent a summarized version of registration procedure (F-81). After the contract is signed, amendments (agreed on by both parties) can be made using form F-78. At this stage, Organization also provides PJR with the following:

a) Written confirmation of preferred dates for the Pre-Assessment (if applicable) and Registration Assessment;
b) Payment of the first installment per the Registration Agreement;
c) A CONTROLLED copy of the facility's Quality Manual. The Quality Manual should be sent to the Lead Auditor a minimum of four weeks before the preferred dates for the Registration Assessment.

If the requirements for registration change at any time, needing retroactive implementation, PJR will ensure Organization is notified and new requirements are followed / implemented at next surveillance.

The Organization may contact PJR to request any reference documents Organization may need such as registration procedure, appeals procedure, etc.

Documentation Review

Within 60 days from receipt of the materials (but in no event less than two weeks prior to the preferred dates for the quality Registration Assessment), PJR carries out a detailed Documentation Review and reports same to the Organization.

This review focuses upon the CONTROLLED COPY of the Organization's Quality Manual:

a) This document must describe the means by which the QMS addresses all requirements of the Standard. In a QS-9000: 1998/TE Supplement/KBA situation, where Organization's quality system goes beyond the requirements of QS-9000: 1998/TE Supplement/KBA in order to meet customer needs, the Quality Manual must also describe the means by which Organization addresses these additional needs.
b) Preferably, this document is a "top tier" manual, making reference to other documented procedures, work instructions, etc. Such secondary and tertiary levels of QMS documentation should not be submitted to PJR in advance of the registration audit unless specifically requested.
c) This document should provide a clear cross-reference to each clause of the Standard, as well as references to any other relevant Standards appropriate to the supplied products and services.
d) At least one complete cycle of management review and internal audit must have been completed before the registration audit, and quality records of management review and internal audit must be submitted as evidence of implementation at the time of document review.

PJR reviews the Quality Manual to assess the degree to which the Organization's QMS conforms to the requirements of the Standard. During this review, PJR auditors may request additional information from the Organization. This review results in one of the following outcomes:

Should PJR determine that the Organization's Quality System addresses the requirements of the standard sufficiently, so as to make it likely that the Registration Assessment will be successful, PJR proceeds with the audit as scheduled.

Should PJR determine that a Registration Audit is likely to be successful contingent upon the prior correction of certain nonconformities, PJR provides Organization with the following:

1) A report citing certain nonconformities that must be addressed with specific corrective actions prior to the Registration Audit (applicable Form F-10). Note that the report <u>will not</u> specify corrective actions to be taken.
2) PJR returns Organization's Quality Manual to the organization bearing the appropriate "PJR Reviewed" stamp or signed off as required on the title and table of contents pages. Copies of these

stamped or signed pages must be filed in client files. Organization will maintain and store manual. (NOTE: If manual reviewed is not a controlled copy, do not stamp. This may require re-submittal of manual to PJR or arrange to do stamping on site during Registration Audit).

Should PJR determine that a Registration Assessment is unlikely to be successful, PJR will inform Organization of same in its report, along with suggestion of certain options, including:

1) The Organization may request PJR to carry out an on-site Pre-Assessment to develop a clearer picture of quality system nonconformities.
2) PJR will conduct no greater than two (2) Pre-Assessments of any individual client facility. For ISO/TS 16949, no more than one (1) pre-assessment take place.
3) The Organization may ask that its Registration Assessment be postponed while it develops and implements corrective actions.

In any of the above situations PJR will place the Organization's application on "hold" status until receiving instructions from the Organization. Applications left on "hold" status for 90 days or longer are discontinued by PJR with written notice to Organization and accrued fees are forfeited to PJR.

Postponement or cancellation of Audits or Pre-Audits by Organization's obligates Organization to pay cancellation fees as specified in F-3.

Registration Audits

No Auditor or Lead Auditor will be assigned or permitted to be a member or the Lead Auditor on any registration activity (Audit) where they have participated in (2) or more preliminary Audits of the registration client.

In accordance with documented procedures that conform with the requirements of EN 45012/G/ISO/IEC Guide 62:1996, ANSI-ASQ Criteria for Accreditation, Clause 7, and ISO 19011: 2002 "Guidelines for quality and/or environmental management systems auditing", PJR appoints a qualified Audit Team. Qualification includes assurance that at least one team member and auditee have same scope. In a QS-9000: 1998/TE Supplement situation qualification includes verification that all team members be QS-9000: 1998/TE Supplement certified by the AIAG, and one member of the team having relevant automotive experience. . For all audits involving the seal of the KBA and the requirements of Road Traffic Law and type approval, one-team member must have attended and passed Road Traffic Law training conducted by the KBA. In a TL 9000 situation, qualification includes verification that all team members have satisfactorily completed a TL 9000 Requirements & Metrics training course sanctioned by QuEST Forum. In an AS9100 situation, all auditors must have been approved through ANAB by the RMC. At least one of the auditors must be approved in this way as an Aerospace Experienced Auditor or Aerospace Industry Experienced Auditor.

Audit Team Leader prepares a specific Audit Plan in conjunction with the Organization. This plan must be provided to the Audit Logistics Manager at PJR – Southfield for review and approval prior to the audit being commenced. The plan may include additional requirements deemed necessary to achieve the required accredited registration.

The Audit Team carries out an audit of the Organization's QMS to assess its conformity to the Standard. Both this visit and subsequent Surveillance audits meet the requirements of ISO/IEC Guide 62:1996; EN 45012, Clause 10 and ANSI-ASQ Criteria for Accreditation, Clause 11. An audit day consists of eight (8) hours, not including lunch and any breaks. The Audit is conducted in accordance with PJR procedures and consists of the following elements:

a) Opening Meeting with Organization's senior management to confirm the scope of registration, review the audit plan and reporting procedures, introduce the Audit Team and to confirm all relevant details for the audit.
b) Detailed examination of the Quality System itself, via personal inspection, document review, and interviews of personnel. During this examination, any observed nonconformities are discussed and reported using PJR Standard Form F-13.
c) Closing meeting, during which the Audit Team's findings are reported to Organization's senior management. Specifically, the audit team:

    1) Presents to Organization copies of outstanding Nonconformity Reports.
    2) Reports to QS-9000: 1998 Organization opportunities for improvements without recommending specific solutions.

The Organization is obligated to assist the Audit Team in the following ways:

a) Provide the Audit Team with quality documentation sufficient enough to lead the audit team to conclude that the quality system is fully documented in accordance with the Standard;
b) Provide the Audit Team with access to facilities, personnel, and records, so the team is able to verify that the Organization's QMS has in fact been established, is being operated and maintained, and is in conformity to the Organization's documentation as well as to the Standard;
c) Cooperate in all ways requested by the Team;
d) Fully resolve all nonconformities.

Upon completion of all Registration Audit activities, PJR will provide Organization with a written Audit Report (F-29), a cover letter including recommendation for certification and Appendix A-1, A-2, A-3, A-4, or A-5 as appropriate.

Resolution of Corrective Action(s)

Types of ISO 9001: 2000 Nonconformities:

a) Major: A total absence of a required system element, a series of minor nonconformities which, taken together, indicate a total breakdown of a required system element, or a situation which would, on the basis of the available objective evidence, raise significant doubt as to the quality of what the organization is supplying.
b) Minor: A single lapse in discipline or control.
c) An Opportunity for Improvement identifies neither a strength nor weakness, but an area that could be improved upon and would be beneficial for the clients overall quality management system. (Corrective action is not mandatory for OFIs)
d) An Observation is another class of audit finding. While not strictly a nonconformity, a finding classified by an auditor as an observation indicates that, in the opinion of the auditor, clarification or investigation is warranted to ensure the overall effectiveness of the system being audited. There is an expectation that observations are addressed through the Organization's preventive action process. (Corrective action is not mandatory for observations)

Types of QS-9000: 1998/TE Supplement Nonconformities:

a) Major is either:
The absence or total breakdown of a system to meet a QS-9000: 1998/TE Supplement requirement. A number of minor nonconformities against one requirement can represent a total breakdown of the system and thus be considered a major nonconformity.
Any noncompliance that would result in the probable shipment of a nonconforming product. A condition that may result in the failure or materially reduce the usability of the products or services for their intended purpose.
A noncompliance that judgment and experience indicate is likely either to result in the failure of the quality system or to materially reduce its ability to assure controlled processes and products.

b) Minor is:
A QS-9000: 1998/TE Supplement noncompliance that judgment and experience indicate is not likely to result in the failure of the quality system or reduce its ability to assure controlled processes or products. It may be either:
A failure in some part of the organization's documented quality system relative to a QS-9000: 1998, or
A single observed lapse in following one item of a company's quality system.

Types of AS9100 Nonconformities:

a) Major:
The absence of, or total breakdown of a management element specified in the AS9100 standard or any nonconformities where the effect is judged to be detrimental to the integrity of the product or service. Also, any minor that is written in an area designated as "critical" must be elevated to a

major nonconformity.

b) Minor
A single system failure or lapse in conformance with a procedure relating to the AS9100 standard, in any area not designated as critical.

The three types of corrective actions are:

a) Those implemented during the course of the Registration Audit. In these cases, the Nonconformity Reports (F-13, original to PJR, copies left with Organization) are completed and signed off during the Closing Meeting.
b) Those involving document or minor changes. These may be implemented without requiring a subsequent Follow-Up Audit. The completed master Nonconformity Reports (F-13) forms must be submitted to PJR, and where applicable, re-evaluation will occur during the first surveillance audit.
c) Those requiring "significant changes" that can be resolved and verified only by means of a subsequent Follow-Up Audit. In these cases, Follow-Up Audits are arranged between PJR and the Organization after Organization submits to PJR the completed master Nonconformity Reports (F-13). The Follow-Up Audit will be limited to the area that was found to be nonconforming.

Clients must submit evidence of corrective action implementation to their Lead Auditor within 60 days of any QMS audit and within 30 days of a QS-9000: 1998 or QS-9000: 1998 w/ TE Supplement audit. Thereafter, PJR may at its discretion repeat the Registration Audit, chargeable at the prevailing PJR Daily Rate (per Schedule of Fees, F-3). Note: All nonconformities, whether Major or Minor, must be closed-out prior to granting registration.

Registration

Upon completion of the Registration Audit, and resolution of any nonconformities as described above, the PJR Audit Team returns all documentation concerning the audit to the PJR – Southfield office. The Audit Logistics Manager (ALM) or designee reviews the packet for completeness. The ALM forwards the Registration Application and associated documentation to the PJR Executive Committee or the Registration Representative with a recommendation either to approve or disallow the registration decision. In a QS-9000: 1998/TE Supplement/KBA/TL/AS9100 situation, the documentation and recommendation must be submitted to an Executive Committee member who has successfully completed the appropriate training; this member has veto power over any certification decision.

In cases where the PM, the Registration Representative or any member of the Executive Committee has been involved in audit activities of the applicant or is for any reason unqualified to or disqualified from making the registration decision, the review and approval process will require and ensure that an appropriately qualified designee conduct the review and approval activities to ensure a sound registration decision is made, free from any conflict of interest.

For audit packages approved for registration by the Registration Representative, or for those forwarded to the Executive Committee for review, (should the Executive Committee concur in a recommendation to extend registration), PJR issues a Registration Certificate of Approval (F-5) specifying the Standard(s) to which the Audit was conducted. The Registration Certificate is valid for a period of three years from the date of issue. After delivery of F-5, a Customer Satisfaction Survey (F-18) is sent to the Organization.

In order to grant TL 9000 registration, at least one data point (3 months' data) regarding appropriate metrics must have been submitted to the QuEST Forum Administrator and written confirmation of the acceptability of the data received.

PJR is the sole authority by which PJR Registration Certificates are granted. Certificates remain the property of PJR.

The Registration Certificate of Approval specifies the scope of the supply (products and/or services) covered by the Registration. Registration under this Scheme does not confer registration or certification of the Organization's products or services, and does not confer registration of any quality management system, process, or supply not specifically enumerated.

If modification of scope is contemplated, Organization must notify PJR in writing of the nature of the proposed modification.

a) A Special Audit may be required to assess such modification. The extent of the Special Audit is

dependent on the degree of modification proposed. The modification request and subsequent Special Audit Report will be reviewed as detailed in Section 10.1, above.

b) Should the Organization need to change or add to his/her scope, the following procedure should be followed:
   i) The Organization notifies the PM in writing of the scope change/addition;
   ii) The Audit Program Department notes the change in the computer file, as well as in the master file;
   iii) The PM ensures that the Audit Program Coordinator (APC) is aware of the scope change so that he/she can notify or change, if necessary, the auditor who performs the Organization's next surveillance audit;
   iv) The scope change/addition and related quality system elements are reviewed at the Organization's next surveillance audit.

The Organization may display the PJR Registration Mark ("Logo") in advertising, promotional literature, and stationery. PJR provides the Organization with camera-ready artwork together with its procedure covering the reproduction and use of the Registration Certificate and Logo, in conformance with EN 45012 Clause 17, ISO/IEC Guide 62: 1996 and ANSI-ASQ Criteria for Accreditation Clause 18, E3.0, as well as the criteria for each Accreditation Body. This procedure (PRO-3) includes, but is not limited to, the following points:

a) The Logo must be reproduced in its entirety, including borderlines, in any proportional size, and in any color;
b) The Logo is used to promote approval of the Organization's QMS and must not be used so as to imply approval of the Organization's product or service;
c) The Registration Certificate and Logo must not be used so as to misrepresent the registration awarded.

PJR, in conformance with EN 45012, Clause 14; ISO/IEC Guide 62:1996 and the ANSI-ASQ Criteria for Accreditation Clause 15, maintains a list of Registered Organizations and their scopes of registration as approved by one of our Accreditation Bodies (Registry F-17). PJR makes this list (F-17) available to PJR's accreditation bodies and the general public, at no charge, upon request. PJR also notifies McGraw Hill Information Services of Organization's registration for inclusion in the "QMS Update" and the McGraw Hill Directory of Registered Companies.

Maintenance of Registration and Surveillance Audits

The Registration Certificate of Approval is valid for a period of three years, subject to continued conformance to the standard. PJR monitors this conformance via regular Surveillance Audits carried out at least once per year. Frequency of Surveillance Audits is in part determined by the size and complexity of Organization's registered facility, and the number and extent of nonconformities observed. Surveillance Audit packages are reviewed under the same process as registration audit packages.

Surveillance Audits are governed by a Surveillance Audit Plan created by the Audit Team assigned after successful completion of the Registration Audit. The plan ensures that all aspects of the organization's QMS – including EA applicable element of QMS are examined at least once during the three-year registration period.

The purpose of surveillance is to verify that the approved QMS continues to be implemented, to consider the implications of changes to that system initiated as a result of changes in the organization's operation and to confirm continued conformity with registration requirements. Surveillance of an organization's QMS shall take place on a regular basis and at least once per year. Surveillance programs should normally include:

a) System maintenance (i.e., internal audit management review and preventive and corrective action);
b) A review of action taken on nonconformities identified during the last audit;
c) Customer complaints;
d) Changes to the documented system;
e) Areas subject to change
f) Other selected areas as appropriate

At each surveillance, PJR should check the following and interview the responsible management.

a) The effectiveness of the QMS with regard to achieving the organization's objective;

b) The functioning of procedures for notifying management of any breaches;
c) Progress of planned activities aimed at continual improvement of system performance;
d) Follow-up of conclusions resulting from internal audits;
e) Use of marks
f) Records of appeals, complaints and disputes brought before PJR and where any nonconformity or failure to meet the requirements of registration is revealed, that the organization has investigated its own systems and procedures and taken appropriate corrective action.

PJR notifies Organization at least 10 working days prior to the proposed Surveillance Audit. The Surveillance Audit follows, in broad form, the same cycle as the Registration Audit.

PJR reserves the right to conduct Special Surveillance Audits during the course of the Registration Period. Circumstances that can trigger Special Surveillance Audits include, but are not limited to:

a) The Organization wishes to extend the Scope of Registration;
b) Complaints from Customers or others suggest to PJR that nonconformities have developed in the elements or the execution of the QMS;
c) Organization implements or wishes to implement a significant change to the QMS.

If the Organization makes minor changes to the QMS, such changes are assessed by PJR during Surveillance Audits by evaluating the changes and the associated documentation.

If the Organization contemplates major changes to the QMS, it must notify PJR which may initiate a Special Audit to ensure that such changes do not conflict with the requirements of the Standard.

At the end of the three-year registration period, PJR conducts a complete reassessment of the QMS, similar to the initial Registration Audit. Such assessments take into account PJR's experience with Organization during the registration period, as well as customer complaints.

The purpose of reassessment is to verify overall continuing effectiveness of the organization's QMS system in its entirety. It is unlikely that a period greater than three years for periodic re-assessment of the organization's QMS would satisfy this requirement. The re-assessment should provide for a review of past performance of the system over the period of registration. The re-assessment program should take into consideration the results of the above review and should at least include a review of the QMS documents and a site audit (which may replace or extend a regular surveillance audits). It shall at least ensure:

a) The effective interaction between all elements of the system;
b) The overall effectiveness of the system in its entirety in the light of changes in operations;
c) Demonstrated commitment to maintain the effectiveness of the system.

IAF Guidance on Guide 62 Reassessment Requirement

The International Accreditation Forum has established new rules mandating reassessment to verify continuing effectiveness of an organization's quality management system. The new rules apply regardless of whether the organization has elected an annual or semi-annual surveillance schedule.

If the organization has elected the continuous (semi-annual) method of surveillance, PJR will conduct the reassessment at the fifth and sixth visits. The amount of time established for reassessment by the new rules is equal to 2/3 of the time mandated for an initial assessment of the organization determined as of the time it is to be reassessed. Reassessment time may vary from the mandated 2/3 figure based on "significant factors that uniquely apply to the organization.", including, but not limited to, these contained in Annex 2 of the IAF Guidance on the Application of ISO/IEC Guide 62. The Guidance document is available on the IAF website at http://www.iaf.nu under "Documentation."

While periodic reassessment must occur in all cases, there may be rare cases in which the reassessment may occur more than three years after the initial assessment. This can only occur where PJR has evaluated, through the adequacy and frequency of surveillance, the overall effectiveness of the quality management system on a regular basis and maintains the necessary level of confidence in it.

All recertification audits are required to be scheduled a minimum of 75-90 days in advance of the certificate expiry date – regardless of whether the client is contracted for continuous (every six months) or Annual (once per year)

surveillance audits.

For both continuous (6 month) and regular (12 month) surveillances, a reassessment is necessary. The APC, upon scheduling a company's 6th surveillance audit, notifies the APM that it is time for that company's reassessment audit using form F-117, Reassessment Audit Notification. The PM or his designee then reviews the contents of the Master File and fills out form F-118, Reassessment (6th Surveillance) Pre-Audit Checklist, showing that all appropriate elements have been reviewed at least two weeks prior to the scheduled audit.

Combined EMS and QMS Audits

EMS and QMS audits may be conducted concurrently by PJR. Ideally there will be a LA who qualifies for both EMS and QMS. However, if not, two separate team leaders should be used, one devoted to quality and the other to environmental auditing. In the event that two teams are used, consecutive opening meetings and closing meetings will be held, with the respective team leader conducting his/her meeting. The combined EMS and QMS teams shall meet all of the applicable qualifications. Only qualified environmental auditors will audit EMS elements. Only qualified quality auditors will audit QMS elements. Audit reporting requirements remain the same as for those audits conducted individually; auditors must clearly and accurately reflect the number of audit days devoted to quality auditing and environmental auditing. Audit reporting is to clearly reflect that all elements of each management system have been fully addressed. Combined audits may be registrations, surveillances, or re-certification audits.

Suspension, Withdrawal or Cancellation of Registration

PJR reserves the right to suspend, withdraw, or cancel the Registration Certificate of Approval at any time during the three year registration period, in accordance with PJR procedure PRO-11, available upon request.

Generally, such actions are considered in the following instances:

a) Organization fails to schedule surveillance audit within required time frame;
b) Organization fails to complete corrective actions during the agreed time frame;
c) Organization persistently fails to conform to Standard;
d) Organization, in PJR's judgment, misuses PJR's Registration Mark, Certificate of Registration, the Accreditation Marks of PJR's accreditation agencies, etc.;
e) Organization becomes delinquent in its financial obligations to PJR;
f) Organization becomes subject to bankruptcy laws or makes any arrangements or composition with its creditors; enters into liquidation, whether compulsory or voluntary; and/or appoints, or has appointed on its behalf, a receiver;
g) Organization is convicted of an offense tending to discredit the Facility's reputation and goodwill, or
h) Organization commits acts that, in PJR's sole judgment, impugn PJR's goodwill, valuable name and reputation.
i) Organization improperly quotes the accreditation and/or registration system in its literature, including advertisements, catalogs and brochures.

PJR will provide Organization with adequate opportunity to implement appropriate corrective actions within a reasonable time frame before withdrawing, canceling, or suspending Registration.

PJR reserves the right to publicize any actions it may take with respect to withdrawal, cancellation, or suspension of a Organization's registration.

PJR will also cancel registration upon the formal written request of Organization.

PJR may take legal action for wrongful actions specified as above.

Witness Assessment

Any organization being audited for the purpose of being issued a certificate containing any Accreditation Body's Seal must permit PJR's audit team to be accompanied by any Accreditation Body's or PJR's auditors for the purpose of

witnessing PJR's audit team.

Disputes and Appeals

Organization or any interested party may dispute/appeal against the decisions of PJR with respect to:

a) Refusal to accept an Organization's application for registration;
b) Failure to confer registration;
c) Suspension, Withdrawal, or Cancellation of Registration;
d) Refusal to extend an Organization's Scope of Approval;
e) An appeal by a third party against PJR's decision to grant registration.
f) Assignment of audit team
g) Or any other issue relevant to the Registration Process.

Appellant may implement the appeal by following PJR Dispute/Appeal Procedure PRO-10, available upon request.

Outline of Requirements

In summary, PJR requires the following from the Organization. The Organization:

a) always complies with the relevant provisions of PJR's certification/registration program;
b) makes all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, reviewing records (including internal audit reports) and interviewing personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;
c) only claims that it is certified/registered with respect to those activities for which it has been granted certification/registration;
d) does not use its certification/registration in such a manner as to bring PJR into disrepute, and does not make any statement regarding its certification/registration which PJR may consider misleading or unauthorized;
e) upon suspension or withdrawal of its certification/registration (however determined), discontinues use of all advertising matter that contains any reference thereto and returns any certification/registration documents as required by PJR;
f) uses certification/registration only to indicate that the quality system is in conformance with specified standards or other normative documents, and does not use its certification/registration to imply that a product or service is approved by PJR;
g) ensures that no certification/registration document, mark or report, or any part thereof, is used in a misleading manner;
h) in making reference to its certification/registration in communication media such as documents, brochures or advertising, complies with PJR's requirements.
i) Any organization being audited for the purpose of being issued a certificate containing any Accreditation Body's Seal must permit PJR's audit team to be accompanied by any Accreditation Body's or PJR's auditors for the purpose of witnessing PJR's audit team.

Confidentiality

Except where required by law, statute, or the regulations of accreditation bodies, PJR treats as strictly confidential any information that comes into its possession in the course of assessment or registration of Organizations' QMS. PJR, including all auditors, administrative staff, Executive Committee, Advisory Board, and any other employee or sub-contractor, promises not to disclose such information to any third party without prior written consent of Organization except when required by law or statute. In the event that law or statute requires such disclosure, PJR will disclose the information as required and inform the Organization of such disclosure in writing in a timely fashion. A confidential Agreement (Promise of Nondisclosure Form F-22) will be signed and retained as evidence of agreement to the requirement of nondisclosure of confidential information.

SCOPE OF ACCREDITATION

Perry Johnson Registrars, Inc., in conformance to ISO/IEC Guide 62: 1996 and the ANSI-ASQ Criteria for Accreditation, evaluates organizations' quality management systems, and, if found to be in conformance, registers them to the appropriate part of the international ISO 9001:2000 quality system standard or QS-9000: 1998/TE Supplement/TL 9000/AS 9100/KBA. These activities are conducted under planned, controlled conditions in accordance with documented procedures and work instructions, as appropriate. *Italics* below indicate an initial scope of accreditation from the respective accrediting body.

SCOPE OF ACCREDITATION (Quality)*

Stitching Raad voor Accreditatie (RvA)
Netherlands

EA No.	**Description**
3	Food products, beverages and tobacco
7	Pulp, paper, and paper products
8	Publishing companies
9	Printing companies
12	Chemicals, chemical products, and fibers
14	Rubber and plastic products
17	Basic metals and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
22	Other transportation equipment
33	Information technology

SCOPE OF ACCREDITATION (Quality)*

ANSI-ASQ National Accreditation Board (ANAB)
U.S.

EA No.	**Description**
01	Agriculture, hunting, forestry and fishing
02	Mining and quarrying
03	Food products, beverages and tobacco; except: NACE DA 16.0, manufacture of tobacco products
04	Textiles and textile products
05	Leather and leather products
06	Wood and wood products
07	Pulp, paper and paper products
08	Publishing companies
09	Printing companies
12	Chemical, chemical products and fibers
14	Rubber and plastic products
15	Non-metallic mineral products
16	Concrete, cement, lime, plaster, etc.
17	Basic metals and fabricated metals products
18	Machinery and equipment
19	Electrical and optical equipment
21	Aerospace
22	Other transportation equipment
23	Manufacturing not elsewhere classified
28	Construction
29	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods, except: NACE G 50.2, maintenance and repair of motor vehicles; and NACE G 52.7, repair of personal and household goods
30	Hotels and restaurants

31	Transport, storage and communications; except: NACE I 64.2, telecommunications (service providers)
32	Financial intermediation, real estate, renting
34	Engineering Services
35	Other services
37	Education
40	Medical devices

Note: Except for NACE G 50.2 and NACE G 52.7, repair and re-manufacture of goods is assumed to be included in the scope category for the manufacture of those goods.

SCOPE OF ACCREDITATION (Quality)*

The Japan Accreditation Board for Conformity Assessment (JAB)
Tokyo, Japan

EA No.	**Description**
3	Food products, beverages, and tobacco
4	Textiles and textile products
5	Leather and leather products
6	Wood and wood products
7	Pulp, paper and paper products
8	Publishing companies
9	Printing companies
12	Chemicals, products and fibers
13	Pharmaceuticals
14	Rubber and plastic products
16	Concrete, cement, lime, plaster, etc.
17	Basic metals and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
22	Other transportation equipment
23	Manufacturing, not elsewhere classified
24	Recycling
28	Construction
29	Wholesale and retail trade, repair of motor vehicles, motorcycles, and personal and household goods
30	Hotels and Restaurants
31	Transport, storage and communication
33	Information technology
34	Engineering services
35	Other services
37	Education
38	Health and social work
39	Other social services

SCOPE OF ACCREDITATION (Quality)*

United Kingdom Accreditation Service (UKAS)
U.K.

EA No.	**Description**
2	Mining and quarrying (limited)
3	Food products, beverages and tobacco (limited)
4	Textiles and textile products (limited)
5	Leather and leather products (limited)
6	Wood and wood products
7	Pulp, paper and paper products
8	Publishing companies
9	Printing companies (limited)

12	Chemicals, chemical products and fibres
13	Pharmaceuticals
14	Rubber and plastic products
17	Basic metals and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
20	Shipbuilding (limited)
21	Aerospace (limited)
22	Other transport equipment (limited)
23	Manufacturing not elsewhere classified (limited)
28	Construction
29	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods
31	Transport, storage and communication
33	Information technology
34	Engineering services
35	Other services
38	Health and social work

SCOPE OF ACCREDITATION (Quality)*

Trägergemeinschatt für Akkreditierung (TGA)

Germany

EA No.	**Description**
3	Food Products, beverages, and tobacco
4	Textiles and textile products
5	Leather and leather products
6	Wood and wood products
7	Pulp, paper and paper products
8	Publishing companies
9	Printing companies
12	Chemicals, chemical products and fibers
14	Rubber and plastic products
17	Basic metals and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
21	Aerospace
22	Other transport equipment
23	Manufacturing not elsewhere classified
28	Construction
29	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods, not NACE 50.3, 52.7
31	Transport, storage and communication, only NACE 60.2, 63.1, 63.2, 63.3
34	Engineering services
35	Other services, only NACE 74.3

SCOPE OF ACCREDITATION (Quality)*

Instituto Nacional de Metrologia, Normalização e Qualidade Industrial - (INMETRO)

Brazil

EA No.	**Description**
4	Textile and textile products
5	Leather and leather products
6	Wood and wood products
7	Pulp, paper and paper products
8	Publishing

9	Printing
14	Rubber and plastic products
15	Non-metallic mineral products
16	Concrete, cement, lime and plaster
17	Basic metals and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
22	Other transportation equipment
23	Manufacturing not elsewhere classified
28	Construction
29	Wholesale and retail trade, repair of motor vehicles, motorcycles, and personal and household goods
31	Transport, storage, and communication
32	Financial intermediation, real estate, and renting
34	Engineering services
35	Other social services
37	Education
38	Health and Social Work

*Since EA codes are broad classifications, PJR may not possess every SIC/NACE code in each of the above EA codes.

SCOPE OF ACCREDITATION

Sistema Nazionale per l'Accreditamento degli Organismi di Certificazione e Ispezione - (SINCERT)
Italy

EA No.	**Description**
3	Food products, beverage and tobacco
4	Textiles and textile products
5	Leather and leather products
10	Manufacturing of coke and refined petroleum products
12	Chemicals, chemical products and fibers
14	Rubber and plastic products
15	Non-metallic mineral products
16	Concrete, cement, lime, plaster, etc.
17	Basic metal and fabricated metal products
18	Machinery and equipment
19	Electrical and optical equipment
21	Aerospace (limited to ground assistance)
28	Construction
29a	Wholesale and retail trade, wholesale on a fee or contract basis
31a	Logistics: transport, storage and shipment
35	Other services