



Perry Johnson Registrars, Inc.

Summary of Quality Management System Certification Procedure

PJR offers certification services to companies, which seek independent validation of their quality systems. Certification to an international quality standard is a detailed and rigorous process. This procedure outlines the certification process from start to finish; detailing a step-by-step approach from initial application to continuing surveillance after certification has been achieved. This procedure also describes a number of PJR policies applicable to varying situations. This document is a summary of PJR controlled procedure PRO-1: Quality Certification Procedure.

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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, 1 st 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:"	4.2

Date	Details	Rev Level
	<p>2000,"QS" and "QS-9000" to "QS-9000: 1998," "TE" to TE 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 <u>made</u>" 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 "<u>Dispute/Appeal</u>" 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/<u>NACE</u> code." SINCERT, added EA 16 and 28.</p>	
04/28/06	Added "EA 03" under SINCERT scope of accreditation	4.3
06/14/06	Pg. 16- Added EA 38 to UKAS list	4.4
10/05/06	Pg. 10- Added PJR Reserves the right...full reassessment.	4.5
08/02/07	Page 4, 5, 6 – Added "readiness review"	4.6
03/21/08	Revised to conform to ISO 17021	4.7
07/25/08	Added OASIS Administrator requirements and 12 month rule for 1 st surveillance audits	4.8
08/08/11	Overall updates of wording/references; Added a statement regarding: submission of required documents prior to audit in "Scheduling Audits" section; and the retention period for the documents obtained from clients in "Confidentiality" section.	4.9
2/28/12	<ol style="list-style-type: none"> 1) Change "registration" to "certification" 2) Change "SINCERT" to "ACCREDIA", Southfield Office to Troy Office 3) Section "Request for Certification" – add a statement that PJR will either accept or decline the application. When PJR declines an application as a result of the review of application, the reason for declining an application will be documented on the Quote Review/Approval Form (F-168) and the reasons will be made clear to the client. 4) Remove references to applicable timetables on F-80 as this document is no longer in use and replace it with "IAF MD 5:2009 Duration of QMS and EMS audits and/or sector specific guidance as applicable" 5) Section "Onsite portion of the Stage I and Stage 2 audits" – add a requirement that each auditor must be accompanied by a guide unless otherwise agreed by the audit team leader and the client. During the audit, the audit team should periodically assess audit progress and exchange information. The Lead Auditor should also reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client 6) Section "Onsite portion of the Stage 1 and Stage 2 audits" – add a statement that if there is available audit evidence to indicate the audit objectives are unattainable and that the LA cannot recommend certification due to presence of an immediate and significant risk, the LA must communicate it to the MR and the Program Manager at PJR to determine appropriate action. This action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or 	

Date	Details	Rev Level
	<p>termination of the audit.</p> <p>7) Section "Onsite portion of the Stage 1 and Stage 2 audits" – add a statement that the LA must assemble the audit team and review audit team's findings as well as other appropriate information collected during the audit against the audit objectives.</p> <p>8) Section "Onsite portion of the Stage 1 and Stage 2 audits" – add a statement that the MR will be given an opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client will be discussed and resolved where possible. Any diverging opinions that are not resolved should be recorded in the comments section of the Auditee Acceptance of Findings Form.</p> <p>9) Section "Certification" – remove a requirement that a member of the Executive Committee must make the certification decision for audit packages where technical review is completed by a Certification Representative, as both have same authority.</p>	
Date 2-13-2015	Details	Rev Level 5.3
	<p>Request for Certification - remove SIC/NACE codes, year version of IAF MD5 and replace it with "latest version", change from 108 to 168 due to a typo, remove reference to form F-78, remove "appeals".</p> <p>Scheduling Audits - remove requirement to return fax, remove sentence stating F-108 serves and the Stage 1 audit plan.</p> <p>Stage 1 audit - add that some sector-specific standards do not allow off-site Stage 1s, F-184 template must be used as the audit plan, remove requirement for client to submit documents to LA electronically.</p> <p>On-Site Portion of the Stage 1 Audit and Stage 2 Audit - remove term for critical nonconformance, observations.</p> <p>Resolutions of Corrective Action(s) - remove definitions of observations, OFIs, critical nonconformance, FSMS definition of an NCR; add requirement to provide objective evidence of correction; overall wording changes.</p> <p>Certification - remove term used for Certification Representatives, reference to ISO 22000, obsolete AS9104A.</p> <p>Disputes and Appeals - remove "appeals".</p> <p>Overall wording/reference update</p>	
	Details	
Date 7-7-2015	<p>Terminology changes were made throughout the entire document. An added requirement states that an addition of a new site to an existing multi-site requires Stage 1 and Stage 2 audits. Reasons for changes were: revisions to ISO 9001: 2015 and the addition of a requirement that was practiced, but not formalized.</p>	Rev Level 5.4

Summary

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

This document also describes the procedure to be followed for an Organization requesting to be certified by PJR during a certification period commenced by a Certification Body other than PJR.

To achieve and maintain certification, 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 certified under this Scheme receives a Certificate and is entitled to advertise and display the appropriate PJR Certification Mark.

The certification 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 Certificate.

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

Request for Certification

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

Client Profile / Questionnaire (F-1)

NOTE: For ISO 14001, OHSAS 18001, ISO 13485, TL 9000, transfer and multi-site quotes, the F-1 Supplement is used in conjunction with the 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 certification process. This document elicits from the Organization the following details, among others:

- a) Contact name (address, etc.)
- b) Scope of certification desired and how the organization wishes it to appear on the certificate (NOTE: minimal changes to the scope will be allowed after the contract has been finalized).
- c) EA code(s)
- d) Description of premises of facility, number of employees, number of work shifts, current projects, yards, their dimensions, outsourced activities
- e) Status of existing quality system

Should the native language of the Organization differ from the native language spoken by the auditor, PJR will always utilize the services of an interpreter.

On the basis of the information furnished by the Organization, PJR will either accept or decline the application. When PJR declines an application as a result of the review of application, the reason for declining an application will be documented on the Quote Review/Approval Form (F-168) and the reasons will be made clear to the client. PJR provides a quotation to cover the cost of the certification and subsequent surveillance visits. The required number of audit days is determined using the latest version of IAF MD 5 Duration of QMS and EMS audits and/or sector specific guidance as applicable. 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 certification process (i.e. a re-visit). It also assumes the accuracy of the information provided by the Organization, and is subject to change to cover additional work by PJR caused by inaccurate or incomplete information.

Transfers are handled in accordance with PRO-13.

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

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

- a) Written confirmation of preferred dates for the Pre-assessment (if applicable) and Stage 1 and Stage 2 audits for initial certification;
- b) Payment of the first installment per the Certification Agreement;

If the requirements for certification change at any time, needing retroactive implementation, PJR will ensure the 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 certification procedure, dispute procedure, etc.

Scheduling Audits

Once the signed Certification Agreement (F-3) is received, the Organization is assigned to an Audit Program Coordinator (Scheduler) for scheduling, based on the dates provided by the Organization. The Scheduler will contact the Organization's Key Contact to set dates for the auditing activities. The Scheduler then coordinates the desired dates with the availability of the auditor(s) possessing the necessary competence. Often, this process takes several contacts between the Organization and the auditor before dates for the auditing activities are mutually agreed upon.

The Scheduler will then send the Organization an Audit Scheduling Acknowledgement form (F-163) for the Organization to sign and return, indicating the Organization's acceptance of the proposed audit dates and the proposed audit team, the background information for which is available upon request. The Organization also has the right to object to the appointment of any particular auditor or technical expert providing the objection is valid (i.e. employee of a competitor, personal differences, etc.). The Scheduler sends the Organization a "request to submit required documented information"; and the Organization then submits the requested information. The information should be submitted by electronic media. The Scheduler also sends the Organization the F-108, which is used by the Organization to make an attestation as to their readiness for the Stage 1 audit. At the time the F-108 is sent to the Organization, the Scheduler also sends the F-191, which is an optional form for the Organization to complete. It helps the Organization confirm that all of their processes address all of the requirements of the given Standard.

Stage 1 Audit

Stage 1 audits are typically 1-2 days in duration. Unless the Organization prefers or logistics are favorable, the first part of the Stage 1 audit (50% of the total Stage 1 time) may be conducted off-site. (Note: some sector-specific standards prohibit off-site Stage 1 audits). The F-184 Audit Plan form must be completed for the Stage 1 audit.

On the day of the audit and at the scheduled starting time, the Lead Auditor should contact the Organization by phone to conduct the opening meeting. The opening meeting should be conducted using the Opening Meeting Agenda. The Lead Auditor should record the Organization's attendance at the opening meeting on the Attendance Sheet. If the Organization hasn't already done so, they must send the Lead Auditor relevant copies of all required information to be reviewed during the Stage 1 audit.

The following are reviewed during a Stage 1 audit:

- The Organization's documented information, including the scope, non-applicability of any standard clauses, identification of interested parties and the interaction between the processes of the management system
- The Organization's identified measurable objectives/targets (i.e. key performance indicators) for ALL of its identified processes
- Evidence that the Organization will have adequate process performance data for all identified objectives by the Stage 2 audit
- Evidence that the Organization's processes address all of the requirements of the applicable standard (Note: The Organization may use the F-191 to meet this requirement or their own equivalent method).
- Evidence that a full system process-based internal audit has been completed. (Note: The Organization must provide objective evidence that all of its identified processes have been audited, likely by process-based audit working documents and perhaps by internal audit nonconformities. The Organization must also be able to provide evidence of corrective action commensurate with the amount of time that has lapsed since the conclusion of the internal audit).
- Competency requirements for internal auditors have been established
- Evidence that a management review (meeting all required inputs and outputs) has been completed after the process-based internal audit.

In order for a Stage 1 audit package to be considered complete and to justify a recommendation to proceed to the Stage 2 audit, a copy of the Organization's sequence and interaction of processes must be included with the Stage 1 audit package. If the Organization has chosen to document how their processes meet all of the requirements of the applicable audit standard (F-191 or equivalent), then this must also be included with the Stage 1 audit package.

At the end of the Stage 1 Audit Report, the Lead Auditor must indicate whether or not the Organization is ready to proceed to Stage 2. The Lead Auditor must also record the contracted Stage 2 days and whether or not the days contracted for the Stage 2 are appropriate, or if s/he would recommend a different amount of time for the Stage 2. Both the Lead Auditor and the Organization must sign the Stage 1 Audit Report.

At this time, the Lead Auditor must also compile the audit plan for the Stage 2 audit on the F-184 template. The processes listed on the Stage 2 audit plan must exactly match the processes listed on the Organization's sequence and interaction of processes. If processes have not been identified by the Organization, then they are not ready to proceed to the Stage 2 audit.

At the scheduled time, the Lead Auditor must hold a closing meeting with the Organization. The closing meeting should be conducted using the closing meeting minutes. The Lead Auditor should record the Organization's attendance at the closing meeting on the Attendance Sheet.

On-Site Portion of the Stage 1 Audit and Stage 2 Audit

Prior to the audit, the Lead Auditor will make contact with the Organization and discuss logistics (travel, preferred start times, etc.), the number of employees and shifts, the scope of audit, the type of attire typically worn by the senior management of the Organization (traditional business, business casual, etc.), and identify special requirements of the audit (such as safety training or gear) as promptly as possible after receiving the assignment. If not already learned on the Stage 1, the Lead Auditor must also ask the Organization where the Organization does business and where the Organization's products or services are sold. The Lead Auditor should familiarize him/herself with the legal and statutory requirements pertaining to the Organization's product or services in all applicable countries.

An opening meeting should be held using the Opening Meeting Agenda. The Lead Auditor should also circulate the Attendance Sheet to document attendance at the Opening Meeting.

The first part of the on-site audit activity is actually the conclusion of the Stage 1 audit. The Lead Auditor from the Stage 1 (who is almost always the Lead Auditor on the Stage 2) must verify corrections taken to address the Stage 1 nonconformities and areas of concern. The Lead Auditor must clearly document the objective evidence reviewed to substantiate that these concerns/nonconformities have been addressed. (Note: The Organization only needs to submit correction on Stage 1 concerns/nonconformities. Root cause analysis and corrective actions are not required). Unless the Stage 1 is conducted entirely on-site, this is also the Lead Auditor's first opportunity to conduct a site tour of the Organization's facility and confirm that the Organization's physical processes match the processes included on the Organization's sequence and interaction of processes.

After completing the on-site portion of the Stage 1 audit, the Stage 2 audit will officially begin. (Note: If audit team members are involved, they may not necessarily be present for the on-site portion of the Stage 1).

A process-based Stage 2 audit then commences in accordance with the audit plan. Any changes to the audit plan should be annotated on the plan and submitted to PJR Headquarters with the audit package. Each auditor must be accompanied by a guide unless otherwise agreed by the audit team leader and the client. During the audit, the audit team should periodically assess audit progress and exchange information. The Lead Auditor should also reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

Every effort should be made to audit the Organization's processes where they occur. Audit evidence gathered through interviews should be verified by acquiring supporting information from independent sources, such as observations, review of documented information and results of existing measurements. Auditors should pick their own samples. Organizations are not allowed to pick them. Sampling by the auditor includes important elements for conducting a value-added audit for the Organization. Adequate sampling can evaluate effective operation of the Organization's management system and identify its weaknesses.

Should objective evidence exist to support writing a nonconformity, the following format should be used:

- Statement of nonconformity,
- Objective evidence observed that supports the statement of nonconformity
- Citation of the requirement(s) not being met.

If the Lead Auditor identifies a major nonconformance during the course of the audit, s/he will notify the Organization immediately. For multiple day audits, the Lead Auditor must have a wrap-up meeting with the audit team and the Organization to discuss a summary of the findings of that day.

Major nonconformities often require a revisit. Whenever the Lead Auditor feels that a major nonconformity has been identified, s/he must immediately contact the Program Manager or a member of the Executive Committee to determine if an on-site revisit is required. The Lead Auditor will then be put in contact with the Scheduling Department to schedule a specific date for the revisit, ideally before the Lead Auditor leaves the Organization's site.

If the available audit evidence indicates that the audit objectives are unattainable and it becomes clear during the course of the audit that the Lead Auditor will be unable to recommend the Organization for certification due to severe deficiencies in the management or due to presence of an immediate and significant risk (e.g. safety), or if it becomes apparent that a revisit will be necessary to close one or more major nonconformities, s/he will communicate that to the Organization and contact the Program Manager at Headquarters to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objective or audit scope, or termination of the audit. The Program Manager or designee and the Lead Auditor will examine the following possible options: a) continue the audit with the understanding that a re-visit may be required or b) discontinue the audit. The Lead Auditor then presents the options to the Organization and makes a recommendation.

After the audit team has concluded the audit itself, but prior to the closing meeting, the Lead Auditor will assemble the audit team and review the team's findings as well as other appropriate information collected during the audit against the audit objectives.

Once the auditor caucus is finished, the results of the audit are presented to the Organization. The Lead Auditor must present the Organization with the NCRs for signature. Audit findings should be reviewed with the Organization with the goal of acknowledging the factual basis of nonconformities prior to the Closing Meeting.

A closing meeting should be held using the Closing Meeting Agenda. The Lead Auditor should also circulate the Attendance Sheet from the workbook to document attendance at the closing meeting. The Organization will be given the opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the Organization will be discussed and resolved where possible. Any diverging opinions that are not resolved should be recorded in the comments section of the Auditee Acceptance of Findings form.

Resolution of Corrective Action(s)

PJR defines the following categories of nonconformities:

Major Nonconformity - QMS - A **major** nonconformity is defined as the absence of, or the failure to implement and maintain, one or more requirements for certification, or requirements of the Organization's management system, which would, on the basis of available objective evidence raise significant doubt as to the credibility of the management system and its capability to achieve its intended outputs; or a number of minor nonconformities against one or more requirements, which, when combined, can represent a breakdown of the management system; or a minor nonconformity that was previously issued and not addressed effectively.

ISMS - nonconformity corresponding to a requirement of the ISMS standard not met (totally or partly), with a potential for security failure

AS9100/9110/9120 - A non-fulfillment of a requirement which is likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products/services; it can be one or more of the following situations:

- a nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
- the absence of or total breakdown of a system to meet a 91XX-series standard requirement, an organization procedure, or customer quality management system requirement;
- any nonconformity that would result in the probable shipment of nonconforming product; and/or
- a condition that could result in the failure or reduce the usability of the product or service and its intended purpose.

Minor Nonconformity - A single observed lapse in the management system.

ISMS - nonconformity corresponding to a requirement of the ISMS standard not met (totally or partly), without risk of security failure

AS9100/9110/9120 -. A non-fulfillment of a requirement which is not likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products/services; it can be either one of the following situations:

- a single system failure or lapse in conformance with a 9100-series standard or customer quality management system requirement; or
- a single system failure or lapse in conformance with a procedure associated to the organization's quality management system.

NOTE: A number of minor nonconformities against one requirement (e.g., similar nonconformities associated to different sites or different departments/functions/processes

within a single site) can represent a total breakdown of the system and thus be considered a major nonconformity.

NOTE for AS Organizations: Effective July 1, 2009, PJR writes a nonconformity to AS Organizations that have not assigned an OASIS Database Administrator PRIOR to the Stage 2 audit or, for existing Organizations, prior to their next surveillance audit. OASIS Administrators can be assigned by logging into the OASIS database, accessing your Supplier Record and completing the section for OASIS Administrator. Failure to do so will result in a nonconformity.

The Organization typically has 60 days from the date of the closing meeting to submit a corrective action plan for **minor** nonconformities found during the course of the audit. The auditor is encouraged to establish an actual date for NCR closure with the Organization and note it on the Audit Report. Note that a corrective action plan includes objective evidence of correction, results of root cause analysis and a plan for corrective action. For **major** nonconformities, the Organization must submit objective evidence of corrective action implementation. Note that there are different rules for aerospace and automotive standards. Please refer to the guidance provided in PJR Advisory #15.

If the Lead Auditor accepts the corrective action response the Lead Auditor must sign the Nonconformity Report. Alternatively, the Lead Auditor may type his or her name. If the Organization's corrective action response is not accepted, then the Lead Auditor is responsible for explaining to the Organization why it was not accepted and reviewing revised submissions.

Certification

Upon completion of the Stage 2 Audit, and resolution of any nonconformities as described above, the PJR Audit Team returns all documentation concerning the audit to the PJR Headquarters. The Audit Logistics Manager (ALM) or designee reviews the packet for completeness. The ALM forwards the Certificate Application and associated documentation to the PJR Executive Committee with a recommendation either to approve or disallow the certification decision. In an ISO 13485/ISO/IEC 27001AS9100 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. For audits requiring certification with ACCREDIA symbol, the documentation and recommendation must be submitted to an Executive Committee Member who has knowledge of the mandatory regulations (if any) applicable to the registrar's schemes/sectors of activity and this member has veto power over any certification decision.

In cases where the PM, 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 certification 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 certification decision is made, free from any conflict of interest. After an affirmative certification decision is made, the audit package is forwarded to a Certificate Coordinator for certificate creation. Certificates are created in accordance with WI-4.

The Organization may display the PJR Certification Mark ("Logo") in paper and electronic promotional media. PJR provides the Organization with camera-ready artwork together with its procedure covering the reproduction and use of the certificate and logo (PRO-3), and the rules from each appropriate accreditation body by which it is accredited.

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

PJR maintains a list of Registered Organizations and their scopes of certification (PJR Registry). PJR makes this list available to PJR's accreditation bodies and the general public, at no charge, upon request. PJR also notifies a number of publications regarding the Organizations certification for inclusion in their publicly available registry lists.

Multi-Site Certifications

Not all Organizations fulfilling the definition of “multi-site organizations” will be eligible for sampling. Addition of a new site to an existing multi-site requires Stage 1 and Stage 2 audits. For example, multi-site aerospace management systems must be sampled in accordance with the guidance provided in AS 9104.

PJR procedures ensure that the initial contract review identifies, to the greatest extent possible, the difference between sites such that an adequate level of sampling is determined in accordance with the provisions below.

Where an organization has a number of similar sites covered by a single management system, a certificate may be issued to the organization to cover all such sites provided that:

- a) All sites are operating under the same management system, which is centrally administered and audited and subject to central management review.
- b) All sites have been audited in accordance with the organization’s internal audit.
- c) A representative number of sites have been sampled by PJR, taking into account the requirements below:
 - i. The results of internal audits of head office and the sites
 - ii. The results of management review
 - iii. Variations in the size of the sites
 - iv. Variations in the business purpose of the sites
 - v. Complexity of the management system
 - vi. Variations in working practices
 - vii. Variations in activities undertaken
 - viii. Potential interaction between the sites
 - ix. Differing legal requirements
- d) The sample should be partly selective based on the above in point c) and partly non-selective and should result in a range of different sites being selected, without excluding the random element of site selection.
- e) Every site included in the management system, which is deemed high risk should be audited by PJR prior to certification.
- f) The surveillance program is designed in the light of the above requirements and, within a reasonable time, covers all sites of the organization or within the scope of the management system certification described in the Certificate.
- g) In the case of a nonconformity being observed either at the head office or at a single site, the corrective action applies to the head office and all sites covered by the certification.

Maintenance of Certification and Surveillance Audits

The 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 a minimum of once per year, the execution of which cannot exceed 12 months from the last day of the Stage 2 audit. The primary purpose of a surveillance audit is to verify the continuing effectiveness and improvement of the Organization’s management system. For this reason, the primary focus of a surveillance audit will include a review of process performance (key performance indicator data) and associated corrective actions, customer complaints, internal audits, management review, improvement and any changes since the last visit. Maintenance of operational control is sampled throughout the surveillance cycle. The Lead Auditor must be certain to answer the surveillance-specific audit questions in the Audit Final Report.

For both 6 month and 12 month surveillances, a reassessment is necessary. A re-assessment should be typically 2/3 of the time spent for the initial audit (Stage 1 and Stage 2).

Surveillance and recertification audits typically follow the same process outlined for Stage 2 audits above.

PJR reserves the right to conduct special or short notice audits during the course of the certification period. Circumstances that may trigger special or short notice audits include, but are not limited to:

- a) Requests for an extension of certification scope – Requests for extension of certification scope often require that the Organization complete a new application (F-1series), or, at the discretion

- of the Program Manager, the Organization may provide an explanation of the extension of certification scope in writing. The Program Manager or designee will review the request for extension of certification scope and the Organization's specific timing request and determine if a special/short notice audit is necessary or if the change can be assessed at the next regular surveillance audit.
- b) Significant changes at the Organization, including changes in ownership, address or key personnel. In response to changes of this nature, a recertification audit is almost always required. (Note that per the PJR contract, the organization is required to notify PJR in writing about any significant change).
 - c) Complaints from customers of certified organizations or interested parties;
 - d) Suspension situations.

The onus is on the Organization to communicate these changes, major or minor, to PJR prior to the auditor arriving onsite. Failure to notify PJR may result in the Organization having to undergo a full recertification audit.

Combined EMS and QMS Audits

EMS and QMS audits may be conducted concurrently by PJR. Ideally, there will be a Lead Auditor who qualifies for both EMS and QMS. However, if not, two Lead Auditors should be used, one devoted to quality and the other to environmental auditing. In the event that two Lead Auditors are used to lead the EMS and QMS teams respectively, 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 certification, surveillance, or re-certification audits. The methodology that PJR has chosen is as follows:

- a) Stage 1 for both ISO 14001 and ISO 9001 will be conducted at the same time. However, any deficiencies found for either standard will delay the Stage 2 for both standards.
- b) Stage 2 for both ISO 14001 and ISO 9001 will be held at the same time.

Suspension, Withdrawal or Cancellation of Certification

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

Generally, such actions are considered in the following instances:

- a) The Organization fails to complete corrective actions during the agreed time frame;
- b) The Organization persistently fails to conform to the appropriate standard;
- c) The Organization, in PJR's judgment, misuses PJR's Certification Mark, Certificate, the Accreditation Marks of PJR's accreditation bodies, etc.;
- d) The Organization becomes delinquent in its financial obligations to PJR;
- e) The 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;
- f) The Organization is convicted of an offense tending to discredit the Facility's reputation and goodwill;
- g) The Organization commits acts that, in PJR's sole judgment, impugn PJR's goodwill, valuable name and reputation;
- h) The Organization improperly quotes the accreditation and/or certification system in its literature, including advertisements, catalogs and brochures.

- i) The Organization is delinquent in scheduling audits

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

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

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

In cases of suspension or withdrawal of its certification (however determined) PJR mandates that the Organization discontinues use of all advertising matter that contains any reference to its certification, and returns any certification documents to PJR Headquarters.

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

Disputes are handled in accordance with PJR procedure PRO-10, available upon request.

Confidentiality

Except where required by law, statute, or the regulations of accreditation bodies, or in the case of aerospace management systems, PJR treats as strictly confidential any information as well as retain documents obtained for six years that come into its possession in the course of assessment or certification of an Organization's management system. PJR, including all auditors, administrative staff, Executive Committee, Impartiality Committee, and any other employee or contractor, promises not to disclose such information to any third party without prior written consent of the registered Organization, except when required by law or statute. In the event that disclosure of such information is required by law or statute, PJR will disclose the information as required and inform the registered Organization of such disclosure in writing in a timely fashion. In the case of aerospace management systems, release of information to regulatory bodies such as the FAA, JAA, or OEM AAQG members may be required.