



Perry Johnson Registrars, Inc.
Quality Systems

Certification Procedure

PJR offers certification services to companies, which seek independent validation of their management 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.

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1 References

- 1.1 ISO/IEC 17021 Conformity assessment - Requirements for bodies providing audit and certification of management systems
- 1.2 JAB MS100-2007 Accreditation Standards for Management System Certification Body
- 1.3 AS9104 Requirements for Aviation, Space and Defense Quality Management System Certification/Certification Programs
- 1.4 ISO/TS 22003 Requirements for bodies providing audit and certification of food safety management systems
- 1.5 ACCREDIA Rules TCN-01, Technical Reports RT-05 .
- 1.6 BS ISO/IEC 27006 Information technology – security techniques – requirements for bodies providing audit and certification of information security management systems
- 1.7 PJR Forms and Procedures: For a complete listing of PJR forms and procedures, refer to SharePoint.
- 1.8 Standard-specific ANAB Accreditation Program Rules
- 1.9 IAF Mandatory Documents
- 1.10 ISO/IEC 20000-6, latest revision

2 Definitions

- 2.1 Applicant - The organization responsible for paying PJR invoices.
- 2.2 Certification Certificate of Approval - A certificate and associated documents affirming that the quality system operated by the applicant has, as a result of the documented assessment procedure conducted by PJR, been found to be in accordance with the specified standards.
- 2.3 Facility Certification - The finding by PJR, resulting in issuance of a Certificate of Approval and publication in the PJR Registry, that the applicant's facility has a system that meets the requirements of the applicable QMS Standard. Further that the applicant's facility uses such system daily, thereby demonstrating to PJR the capability of consistently adhering to the requirements, as well as the commitment to the goals of the requirements, of the QMS Standard. Certification makes the facility part of the PJR QMS Certification System, subject to the terms and conditions of the contract between PJR and the organization, and all applicable rules and regulations relating to such certification.
- 2.4 Facility - A specific firm, physical location, corporate entity, or individual that has been granted a Certificate of Approval.
- 2.5 Organization's Key Contact - A facility employee that is appointed as the primary point of contact as it pertains to the certification process.
- 2.6 QMS Series of Quality Management and Quality Assurance Standards - The quality management systems standards published by the International Organization for Standardization, the SAE Aerospace Group, and also published in equivalent forms by various national organizations. For example, AS9100 - The Aerospace derivative of ISO 9001 plus additional

elements developed by aerospace industry stakeholders.

- 2.7 Preliminary Assessment (Pre-assessment) - An informal facility evaluation carried out by PJR to assess the facility's overall QMS prior to the Stage I Audit. The objective of a pre-assessment is to determine the readiness of an organization for certification.
- 2.8 Quality Management System - The organizational structure, responsibilities, documented information, processes, and resources for implementing quality management.
- 2.9 Certification Mark - The logo, authorized by PJR for use by a certified facility, publicizing that the facility has proven its compliance with the specified QMS Series Standard for a specific scope of activity.
- 2.10 Registry - List of facilities and their associated product(s) and/or service(s) that are certified under PJR's procedures (available upon request).
- 2.11 Continued Assessment/Surveillance Audit - Post certification visits by PJR assessors to determine continued conformity to the specified Standard(s).

3 Request for Certification

- 3.1 The organization initiates the Certification Process via a written or verbal request for information. In response, PJR provides the organization with the following: F-1 Client Profile/Questionnaire (and/or other applicable PJR application form)

NOTE: For multi-sites, ISO 13485 and ISO 14001 quotes, the F-1 Supplement is used in conjunction with the F-1 Application form. Sector-specific F-1 forms exist for some specialized standards.

PJR will also supply the customer with additional PJR certification system documentation/information, if needed, upon request.

- 3.2 The organization completes the applicable PJR standard form F-1 (or PJR takes information by phone) to provide PJR with the initial information required to commence the quotation/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) –**EA codes are very important. They are used by Scheduling to ensure a competent auditor is assigned.**
 - 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 auditee differ from the native language spoken by the auditor, PJR will always utilize the services of an interpreter.

If the client has more than one location, the information on the F-1supp will be used to determine the type of multi-site. The following describes the differences in certification structures:

Single site:

IAF MD 1 defines a site as “all land on which processes/activities under the control of an organization at a given location are carried out...” One building is easily understood to be a single site. Multiple buildings at a given location could also be considered to be a site.

Note: PJR does not define a distance between buildings that can be considered a given location.

Multi-Site where sampling can be applied:

A multi-site is an organization having an identified central function (a central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, managed or at which such activities are fully or partially carried out. Except for the central office, the processes at all the sites have to be basically of the same kind and have to be operated by identical methods. (See the definition and the eligibility of the “Multi-site Organization” in IAF MD 1).

Sampling shall be partially selective to ensure that all processes covered by the scope of certification will be audited. Additionally, at least 25% of these sample shall be selected at random.

Site selection shall take into account risk (performance on prior audits, complaints, etc.), known changes in the management system and differences due to geography (culture, language and legal and other requirements). The sampling plan/strategy, as well as the audit time for each site sampled, shall be documented on the F-114.

The central function is audited at the initial audit, at recertification and at least once during a surveillance year. The number of sites to be visited is based on the following:

-for initial audits: the sample size is the square root of the number of sites, rounded to the nearest whole number.

-for surveillance audits: the sample size is 60% of the square root of the number of sites, rounded to the nearest whole number.

-for recertification audits: the sample size is the same as an initial audit. If the management system demonstrates good performance over the course of the certification cycle, then 80% of the square root for the number of sites, rounded to the nearest whole number can be sampled.

To add an additional site(s) to an already certified scheme where sampling is appropriate, consideration needs to be given as to the extent of auditing. The chosen strategy shall be documented on the appropriate F-114. Not all sites may need to be audited.

Calculating audit time for sites where sampling can be applied:

Audit time for a specific site is based on that site's employee count and risk level. IAF MD 5 allows for a discount of up to 30%. Unless disallowed by a specific sector, the maximum discount that can be applied to a given site is 50%. This means 20% is to be considered the maximum reduction allowed for management system processes being performed by onl the central function.

Multi-Site where sampling CANNOT be applied:

Here, the organization also has an identified central function (a central office, but not necessarily the headquarters of the organization) at which certain activities are planned, controlled, managed or at which such activities are fully or partially carried out. However, the processes at the sites are substantially dissimilar, such that sampling cannot be justified.

At the initial and recertification audit, all sites must be audited. In surveillance years, 30% of the sites rounded up to the nearest whole number must be audited in a calendar year. The central function must be included. The sites audited during the second surveillance will normally be different.

To add an additional site(s) to an already certified scheme where sampling cannot be applied, the site(s) must be audited before inclusion on the certificate.

Calculating audit time for sites where sampling is not applicable:

Audit time for a specific site is based on that site's employee count and risk level. IAF MD 5 (and many other sector-specific rules) allow for a discount of up to 30%. Unless disallowed by a specific sector, the maximum discount that can be applied to a given site is 50%. This means 20% is to be considered the maximum reduction allowed for management system processes being performed by only the central function.

It is possible that a multi-sited organization may consist of sites where sampling can be applied and sites where sampling cannot be applied.

For AQMS certification programs, several sites and complex site schemes also exist. Information on these schemes can be found in AS9104-1 and WI-14. When quoting AQMS, the Sales Coordinator must demonstrate that the correct classification was chosen by completing the F-215, Aerospace Scheme Classification.

For ISO 13485, design and development and manufacturing sites cannot be sampled.

For AS9100 and AS9110, no sampling is allowed on initial and recertification audits. 50% of the sites must be audited at the first annual surveillance and 50% of the sites must be audited at the second annual surveillance. For AS9120, sampling is allowed in accordance with IAF MD 1. However, all sites must be audited in a given certification cycle.

- 3.3 If the scope of activity of an applicant organization is similar to PJR's own description of business, PJR will not accept the application. Verification of the resources and competencies necessary to provide certification to an applicant organization is required and if PJR cannot confirm its own competence / resources to certify an applicant organization, PJR will refuse to accept the application.
- 3.4 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 reasons 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. When PJR accepts an application, PJR will determine the audit objectives, scope, and criteria and provide a quotation to cover the cost of the certification and subsequent surveillance visits:
 - 3.4.1 The required number of audit days is determined using the IAF MD5 (IAF Mandatory Document for Duration of QMS and EMS Audits)).
 - 3.4.2 For AS91xx, the audit time listed in Table 2 of AS9104-1 must be quoted.
 - 3.4.3 For TL 9000, the guidance provided in the *TL 9000 Auditor Time* document must be followed.
 - 3.4.4 For ISO 13485, Annex D of IAF MD 9 must be followed.
 - 3.4.5 For BA 9000, 30% must be added to the adjusted IAF MD 5 days for ISO 9001.

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 organization, and is subject to change to cover additional work by PJR caused by inaccurate or incomplete information.

- 3.5 Deviations (+ or -) to the required audit days require documented justification. For ISO 9001 audits, reasons for reduction can be found in OM-06-09 and may include the following:
 - Organization is not design responsible and/or other Standard elements are not covered in the scope.
 - No/low risk product/processes
 - Prior knowledge of organization system (e.g. already certified by PJR to another Standard – further detail regarding combined audits can be found in

WI-35).

- Very small site for number of employees (e.g. office complex only)
- Client preparedness for Certification (e.g. already certified or recognized by another Third Party Scheme)
- Combined or integrated audit of two or more compatible management systems (See section 3.4.3)
- Low Complexity activities (e.g.
 - Process involves a single generic activity (Service ONLY)
 - Identical activities performed on all shifts with appropriate evidence of equivalent performance on all shifts based on prior audits (internal and 3rd party)
- Maturity of management system
- High percentage of employees doing the same, simple tasks
- Where staff include a number of people who work “off location” (e.g. salespersons, drivers, service personnel, etc.) and it is possible to substantially audit compliance of their activities with the system through review of records.

Reasons for additional time may include the following:

- Complicated logistics involving more than one building or location where work is carried out (e.g. a separate Design Center must be audited). For example, a campus scheme may have increased complexity due to having more than one location.
- Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently)
- Very large site for number of employees (e.g. a forest or large, primarily automated facility)
- High degree of regulation (food and drugs, aerospace, nuclear power, etc.)
- System covers highly complex processes or relatively high number of unique activities
- Activities that require visiting temporary sites to confirm the activities of the permanent site(s) whose management system is subject to certification

Justification for quoted audit days must be recorded on an F-114 form that must be approved by the Programs and Accreditations Manager or appropriate designee Manager, International Audit Program Coordinator of the Latin American Division (authorized to approve only ISO 9001 quotations), the Manager of the Italian Division or the Sales Coordinator, as appropriate. Sales Managers must also have a technical reviewer sign off on a quotation. After the quote is compiled and the F-114 completed, results of the quotation review are documented on the F-168, Quote Approval Checklist.

3.4.2 Transfers are handled in accordance with PRO-13.

3.4.3 A combined audit is an audit of an organization’s management system(s) against two or more sets of audit criteria/standards conducted at the same time. An integrated management system results only when an organization uses a single management system to manage multiple aspects of organizational performance, to meet the requirements of more than one management system standard. To determine audit time for an audit covering more than one management system, the requirements of IAF MD 11 must be followed.

- PJR reserves the right to increase audit time where reductions are taken based on declared levels of management system integration that are subsequently found to be invalid. The level of management system integration will be confirmed at Stage 1. Thus, audit time may be adjusted prior to the Stage 2 audit.

- For Multi-Site, audit days are determined based on the standard audit day chart according to the effective number of employees at each site. Sampling could be applied for the multiple sites offering similar products, services, processes or activities at each site (See IAF MD1). When nonconformities are found during site sampling, corrective action should be applied to all affected sites including those not physically audited.
- 3.5 For FSMS quotations: The use of multi-site sampling is only possible for organizations with more than 20 sites and only for categories A, B, E, F and G. This applies both to the initial certification and to surveillance audits. Where PJR offers multi-site certification, PJR shall utilize a sampling program to ensure an effective audit of the FSMS where
- a) the sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites with a minimum of 20. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming (i.e. not meeting certification thresholds for ISO 22000),
 - b) evaluation of the audit findings of the sampled sites shall be deemed equivalent to the internal audit findings of the same sites of the organization
 - c) at least annually, an audit of the central FSMS shall be performed
 - d) at least annually, surveillance audits shall be performed on the sampled sites, and
 - e) audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.
- 3.6 Should the organization wish to proceed with certification, PJR provides a copy of the appropriate Registration Agreement and F-3tc. The organization then completes, signs, and returns a copy of the appropriate Certification Agreement bearing an original signature. The receipt by PJR of this document is taken as an instruction to proceed in accordance with the appropriate Certification Agreement and associated procedures, and they are sent a summarized version of the Certification Procedure (F-81series). (After the contract is signed, amendments (agreed on by both parties) can be made using form F-78.) 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 Assessments;
 - b) Payment of the first installment per the Certification Agreement;
- 3.7 For FSMS clients: contract review shall be performed after receipt of signed Certification Agreement by personnel that have successfully completed training in
- a) hazard analysis and critical control point (HACCP) principle, hazard assessment and hazard analysis
 - b) food safety management principles including prerequisite programs (PRPs), and
 - c) relevant FSMS standards.
- Any necessary changes to the contract will be made my amendment after the contract review is conducted.
- 3.8 If the requirements for certification change at any time needing retroactive implementation, PJR will ensure that the organization is notified and the new requirements are followed/implemented at the organization's next surveillance audit.
- 3.9 Any difference in understanding between the certification body and the applicant is resolved.
- 3.10 Clients interested in ISO 27001 certification should complete the F-1sec. The Information Security Program Manager is responsible for completing the appropriate F-114, Audit Day Justification, based on the audit table in ISO/IEC 27006. Risk and possible adjustments to audit time are calculated using the F-114sec, Complexity Worksheet. Discounts to audit time above that stipulated by ISO/IEC 27006 are not allowed. The technical area(s) of the organization is determined at the quoting stage and documented in the client's profile in

PJView. This can be compared to ISMS auditors' competencies in these technical areas, which are also documented in PJView, to ensure a competent auditor and technical reviewer are assigned.

- 3.11 Clients interested in ISO/IEC 20000-1 certification should complete the F-1itsms form. Annex A of the F-1itsms form must be completed if any processes, or parts of processes, within the SMS are operated by other parties. The ITSMS Program Manager is responsible for completing the F-114itsms Audit Day Justification based on the audit table in ISO/IEC 20000-6. Factors for reducing audit time are described in Table 2 of ISO 20000-6. Factors for increasing audit time are described in Table 3 of ISO 20000-6. If a client is certified to another **relevant** management system standard, e.g. ISO 9001 and/or ISO 27001, then a discount for **initial audit time** can be given if the existing certification is current and has been audited by an accredited certification body at least once in the last twelve months and the scope of certification of the other relevant standard is equivalent to or greater than the 20000-1 scope. The amount of discount should reflect the level of integration.

For multi-sited organizations, quoting needs to consider the following: difference in services provided, differences in site size, differences in language, local variations of the SMS, legal and regulatory requirements and other parties involved in the provision of services and temporary sites covered by the SMS but not in the scope of certification.

4. Scheduling Audits

- 4.1 Once the signed Certification Agreement 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 Management Representative 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 client and the auditor before dates for the auditing activities are mutually agreed upon. The Scheduler or appropriate Manager is responsible for justifying the auditor assignment using the F-114a for all standards.
- 4.2 The Scheduler will then send the client an Audit Scheduling Acknowledgement form (F-163) or equivalent document for the client 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 client 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 presence and justification of observers (i.e. client's consultants, witnessing accreditation body personnel, regulators or other justified persons) will be agreed to by PJR and the client prior to the audit. The Scheduler also sends the client the appropriate F-108, which is used by the client to make an attestation as to their readiness for the Stage 1 audit, as well as serving as the Stage 1 audit plan. At the time the appropriate F-108 is sent to the client, the Scheduler also sends the F-191, which is an optional form for clients to complete. It helps the client confirm that all of their processes address all of the requirements of the given Standard.
- 4.2.1 After the F-108as is returned, the three-year audit program is completed in PJView prior to the Stage 1 audit. After this is completed, the F-108as and related attachments are uploaded in SharePoint for the Lead Auditor.
- 4.2.2 For ISO 27001, we create the client's audit program in PJ View by using the each numbered clause title of the standard as a process (i.e., Context of the organization, Leadership, Planning, etc.), as well as, each annex a control whole number as a process (A.5, A.6, A.7...A.18).
- 4.2.3 For ISO 20000-1, the F-108itsms will assess the site-to-site differences and ensure an appropriate sampling strategy.
- 4.3 The Scheduler then creates an Auditor Assignment Form (F-27*) and forwards it to the auditor(s) after approval by Customer Service or appropriate international designee. (*Japan Division: The Scheduler creates an Auditor Assignment Form (F-54J) and forwards it to the auditor(s). F-54J must be approved by a person other than its creator.

5 Stage 1

- 5.1 Stage 1 audits are typically 1-2 days in duration. Unless the auditee prefers or logistics are favorable, the first part of the Stage 1 audit is conducted off-site. F-184 shall serve as the audit plan for the Stage 1 audit. AS9100, AS9110, ISO 22000 and ISO 27001 Stage 1 audits are always conducted on-site. Where audits are conducted on-site, each auditor must be accompanied by a guide unless otherwise agreed by the audit team leader and the client. The audit team must ensure that the guides do not influence or interfere in the audit process or outcome of the audit.
- 5.2 On the day of the audit and at the scheduled starting time, the Lead Auditor should contact the auditee by phone to conduct the opening meeting. The opening meeting should be conducted using the Opening Meeting Agenda in the audit workbook supplement. The Lead Auditor should record auditee attendance at the opening meeting on the Attendance Sheet. If the auditee 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. Ideally, the auditee will submit it to the Lead Auditor electronically.
- 5.3 The following are reviewed during a Stage 1 audit:
- 5.3.1 The auditee's documented information, including the scope, non-applicability of any standard clauses, identification of interested parties and the sequence and interaction between the processes of the management system
 - 5.3.2 The auditee's identified measurable objectives/targets (i.e. key performance indicators) for ALL of its identified processes
 - 5.3.3 Evidence that the auditee will have adequate process performance data for all objectives listed in 5.3.3 by the Stage 2 audit
 - 5.3.4 Evidence that the auditee's processes address all of the requirements of the applicable standard (Note: The auditee may use the F-191 to meet this requirement or their own equivalent method). If the auditee chooses not to complete the F-191 or an equivalent form, then the auditee must identify which of their processes address the requirements of the audited standard, perhaps on the sequence and interaction of processes.
 - 5.3.5 Evidence that a full system process-based internal audit has been completed or evidence that an audit will be completed by the Stage 2 audit (i.e. an audit schedule).
 - 5.3.6 Competency requirements for internal auditors have been established
 - 5.3.7 Evidence that a management review (meeting all required inputs and outputs) has been completed after the process-based internal audit or evidence that the management review will be completed by the Stage 2 audit.
- 5.4 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 auditee's sequence and interaction of processes must be included with the Stage 1 audit package. If the auditee 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.
- 5.5 The results of the Stage 1 audit are to be documented on the Stage 1 Audit Report, which is included in the appropriate Stage 1 Audit Workbook. At the end of the Stage 1 Audit Report, the Lead Auditor must indicate whether or not the auditee is ready to proceed to Stage 2. The Lead Auditor must also record the contracted Stage 2 days (which will be listed on the F-27*, Auditor Assignment Form) 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 auditee must sign the Stage 1 Audit Report. (* Japan Division: F-54J shall be used instead of F-27)
- 5.6 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 auditee's sequence and interaction of processes. If processes have not been identified by the auditee, then they are not ready to proceed to the Stage 2 audit. (If recommending that the auditee is ready to proceed to the Stage 2 audit, a copy of the Stage 2 audit plan must be included in the Stage 1 audit package).
- 5.7 At the scheduled time, the Lead Auditor must hold a closing meeting with the auditee. The closing

meeting should be conducted using the closing meeting minutes in the audit workbook supplement. The Lead Auditor should record auditee attendance at the closing meeting on the Attendance Sheet.

- 5.8 The completed audit workbook, the copy of the auditee's sequence and interaction of processes, evidence that the auditee's processes meet all the requirements of the applicable standard (if the auditee has chosen to do this) and a copy of the Stage 2 audit plan, if recommending that the auditee is ready to proceed, must be uploaded to SharePoint within one week of the audit. (Note: International divisions may have different requirements for audit package submission).
- 5.9 Unless the Lead Auditor has been granted authority to recommend the client to proceed to Stage 2, a member of the Executive Committee will review the Stage 1 audit package and make the decision on whether or not the client is truly ready to proceed to the Stage 2 audit. (Note: For some standards (e.g. ISO 22000), PJR will also involve a technical reviewer as part of the System Review team in the decision of readiness to proceed to Stage 2). The Executive Committee's decision is documented on the bottom of the Stage 1 Audit Report, and a record of the decision is entered into PJView, which prompts Scheduling to schedule/confirm the Stage 2 audit. If the Stage 2 time is changed from the time that is contracted, then a request for amendment must be made to the Sales Coordinator.
 - 5.9.1 Stage 1 audits may result in a decision of ready to proceed, but with the auditor wanting to review objective evidence that any Stage 1 concerns have been contained prior to the Stage 2. This can be accomplished by either an on-site or off-site revisit. Both are scheduled events with dedicated time. The Lead Auditor must communicate the need for a revisit to the appropriate Program Manager or Scheduler.
 - 5.9.2 In some cases the Stage 2 is already scheduled when the Stage 1 is conducted. The results of the Stage 1 may necessitate postponing the Stage 2. The Lead Auditor should clearly communicate this to the auditee. In cases where significant changes occur to the management system due to the results of the Stage 1 or the time interval between the Stage 1 and Stage 2, it may become necessary to repeat the Stage 1.

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

- 6.1 Only after the Lead Auditor receives the F-27 (Japan Division: F-54J) for the Stage 2 audit should s/he consider it confirmed. (There may be instances where the Lead Auditor recommends that the auditee is ready to proceed to Stage 2, but the Executive Committee decides that the auditee is not). Receipt of an F-27 (Japan Division: F-54J) for the Stage 2 audit is the Lead Auditor's confirmation that Executive Committee concurs with the Lead Auditor's Stage 1 recommendation.
- 6.2 Prior to the audit, the LA will make contact with the auditee and discuss logistics (travel, preferred start times, etc.), the type of attire typically worn by the senior management of the auditee (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 LA must also ask the client where the client does business and where the client's products or services are sold. The LA should familiarize him/herself with the legal and statutory requirements pertaining to the client's product or services in all applicable countries. A web search is the best way to accomplish this, for example www.epa.gov, www.fda.gov, www.cfqlcs.go.jp (Center for Food Quality, Labeling and Consumer Services) or www.n-shokuei.jp (Japan Food Hygiene Association). The Lead Auditor should also contact any audit team members to relay logistical arrangements, dress code issues, etc. and provide the client and all audit team members of copy of the Stage 2 audit plan.
- 6.3 An opening meeting should be held using the Opening Meeting Agenda in the workbook supplement. The Lead Auditor should also circulate the Attendance Sheet to document attendance at the Opening Meeting.
- 6.4 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 off-site 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 auditee need only 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 auditee's facility and confirm that the auditee's physical processes match the processes included on the auditee's sequence and interaction of processes. The results of this on-site Stage 1 activity should be documented on the Verification of Stage 1 Nonconformities/ Areas of Concern section in the Stage 2 audit workbook.

- 6.5 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).
- 6.6 A process-based Stage 2 audit then commences in accordance with the audit plan. The Lead Auditor should ensure that the team member with competence in the auditee's process (i.e. the team member with competence in the EA code of the auditee) is assigned to audit the technical processes of the auditee. Each auditor must be accompanied by a guide unless otherwise agreed by the audit team leader and the client. The audit team must ensure that the guides do not influence or interfere in the audit process or outcome of the audit. 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. The Lead Auditor should also ensure that appropriate time is scheduled for audit team meetings, etc. Please note that only 10% of the total on-site time should be dedicated to report writing activities on a QMS audit. Any changes to the audit plan should be annotated on the plan and submitted to PJR Headquarters with the audit package.
- 6.7 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. The names, job titles and working shifts of those interviewed are to be recorded on the audit working document within the audit workbook. The audit team must record copious notes of conformity and nonconformity on the audit working document. If the audit performed is a multi-site audit, the audit working document must indicate which site is being assessed. Notes must be organized in accordance with the processes of the organization and not the clauses of the standard being audited. Insufficient or clause-based audit working documents are not acceptable and will be rejected by the Executive Committee.

Auditors should pick their own samples. Clients are not allowed to pick them. (Please refer to PJR Advisory #21, Auditor Notations on Client Documentation & Documentation Sampling). Sampling by the auditor includes important elements for conducting a value-added audit for the auditee. Adequate sampling can evaluate effective operation of the auditee's management system and identify its weaknesses. It is important to keep in mind that the term "sampling" suggests a somewhat random selection of evidence within a specific process. Because of this, auditors must remember to "actively" select those processes that preliminary review has shown to be associated with customer complaints, returned product, or internal nonconformity. Historical performance (or lack of) should help provide a "focus" for where sampling should be conducted. For example, the auditor may wish to sample the effectiveness of inspection processes in 2 of 5 product lines--- in such a case, the auditor should determine if there were any customer or internal nonconformities to product, and choose at least one of those product lines to audit.

- 6.7.1 If the organization cannot make a process or documented information available for review, because of confidentiality or security concerns, then the Lead Auditor must contact the appropriate Program Manager at Headquarters. Together, they will make the decision if the management system can be adequately audited in the absence of these items. Any activities that cannot be verified cannot be included in the scope of certification. If these activities represent exclusions that are not permissible, then certification may not be possible.
- 6.8 Should objective evidence exist to support writing a nonconformity, the following format should be used:
 - 6.8.1 Statement of nonconformity,
 - 6.8.2 Objective evidence observed that supports the statement of nonconformity and
 - 6.8.3 Citation of the requirement(s) not being met.

6.9 PJR defines the following categories of nonconformities:

- 6.9.1 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 the policy and objectives of the organization; 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.

FSMS - nonconformity corresponding to a requirement of the FSMS standard not met (totally or partly), with a potential impact on the safety of the products

FSSC – nonconformity that negatively affects the capability of the management system to achieve the intended results

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

AS9100/9110/9120 – In addition, a major nonconformity may exist 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 9100-series requirement, a customer requirement or documented information defined by the organization; any nonconformity where probable delivery of nonconforming product or service may result and any condition that can result in the failure or reduce the usability of the product or service and its intended purpose.

- 6.9.2 Minor Nonconformities - A single observed lapse in the management system.

FSMS - nonconformity corresponding to a requirement of the FSMS standard not met (totally or partly), without impact on the safety of the products

FSSC – nonconformity that does not affect the capability of the management system to achieve the intended results

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

AS9100/9110/9120 - A single system failure or lapse in conformance with a relating to the applicable standard.

- 6.9.3 FSSC – Critical nonconformity – circumstance in which direct food safety impact without appropriate action by the organization is observed during the audit or when legality and/or certification integrity area as stake

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

6.11 If a member of the audit team identifies a suspected major nonconformance during the course of the audit, s/he must notify the LA immediately. (Team members are expected to refrain from classifying nonconformities during the course of the audit; classifying nonconformities is the responsibility of the Lead Auditor, who makes final determination of nonconformities and their severity).

6.12 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, member of the Executive Committee or other appropriate international contact 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 auditee's site.

6.13 If the available audit evidence indicates that the audit objectives are unattainable and it becomes clear during the course of the audit that the LA will be unable to recommend the auditee for certification due to severe deficiencies in the management system or due to the 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, it is important that s/he communicates that to the auditee and contacts the Program Manager at Headquarters to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. If the Program Manager is not available, select the next appropriate designee from the Headquarters Reporting List. The Program Manager or designee and the LA 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 auditee and makes a recommendation. It is important that the decision be communicated to the Program Manager immediately, as often these situations require contractual modifications.

- 6.14 The Lead Auditor, with input from the audit team, must complete the Audit Final Report, and in the case of aerospace audits, any sector-specific reporting documents.
- 6.15 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. The Lead auditor must review the Audit Working Document to ensure that all clauses of the standard were audited, and were audited appropriately. The Lead Auditor reviews the Nonconformity Reports (NCRs), makes whatever modifications are necessary and numbers the NCRs (each NCR issued receives a sequential number).
- 6.16 At this point, the audit team turns over to the Lead Auditor all audit working documents and other required forms, including the Statement of Availability, Confidentiality and Promise of Non-Disclosure.
- 6.17 Once the auditor caucus is finished, the auditee is called in and the results of the audit are presented to him/her. The Lead Auditor must present the auditee with the NCRs for his/her signature. Audit findings should be reviewed with the auditee with the goal of acknowledging the factual basis of nonconformities prior to the Closing Meeting.
- 6.18 At that point, the next surveillance audit should be scheduled with the auditee. If time permitting, call the (Scheduler) and have the dates scheduled immediately and fill out the Auditor Scheduling Form. Note: This may not be required by some International divisions.
- 6.19 A closing meeting should be held using the Closing Meeting Agenda in workbook supplement. The Lead Auditor should also circulate the Attendance Sheet to document attendance at the closing meeting. The auditee will be given an opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit teams 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.
- 6.20 The Lead Auditor and auditee should acknowledge the execution of critical audit events and all documented nonconformities on the Auditee Acceptance of Findings form. In the case of aerospace audits, the Lead Auditor must complete any nonconformity reports and associated PEARs.
- 6.21 The Lead Auditor must upload the complete audit package to SharePoint within one week of the last day of the audit. Auditors should follow the guidance in PJR Advisory #6 when submitting audit packages. (Note: International divisions may have different requirements for audit package submission).
- 6.22 The auditee 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 unless sector-specific rules mandate different deadlines. For food safety audits corrective action plan with objective evidence is required for both types of non-conformities (The auditor is encouraged to establish an actual date for NCR closure with the customer and note it on the Audit Report). Note that a corrective action plan includes a plan for correction, results of root cause analysis and a plan for corrective action. For **major** nonconformities, the auditee 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.
- 6.23 For multi-site audits, the organization shall consider if the corrective action is specific to a site or if it must be applied across all sites. If the implementation of the corrective action is limited

to a single site, then the organization shall justify this in its response.

- 6.24 If the Lead Auditor accepts the corrective action plan (for minor nonconformities) or evidence of corrective action implementation (for major nonconformities), the Lead Auditor must and sign the portion of the Nonconformity Report called "CA Plan is Accepted". Alternatively, the Lead Auditor may type his or her name. If the client's corrective action plan is not accepted, then the Lead Auditor is responsible for explaining to the auditee why it was not accepted and reviewing revised submissions. Regardless whether or not acceptable corrective action plans (or acceptable evidence of corrective action implementation) are received, the Lead Auditor is responsible for uploading the auditee's corrective action plans/evidence to SharePoint within 75 days of the last day of the audit. If the auditee's corrective action plans/evidence are not acceptable, then the Lead Auditor must notify their ASA.
- 6.24.1 If the Lead Auditor is not able to verify the implementation of corrections and corrective actions of any **major** nonconformities within six months after the last day of the Stage 2, then PJR must conduct another Stage 2 prior to recommending certification. Corrective action plans have never been acceptable for major nonconformities, but now there is a time limit for implementation of corrections/corrective actions in a Stage 2.
- 6.24.2 In the case of aerospace audits, auditor acceptance of corrective actions must be documented on the Nonconformity Report itself. Timing requirements specified in AS9101 must be followed.
- 6.25 If a revisit audit is necessary, then the Revisit Report within the audit workbook must be completed. The header of the audit workbook must include both the original audit number and the revisit audit number. If the auditor is unable to close a major nonconformity on a revisit audit, then the appropriate Program Manager must be contacted. The major shall remain open. The appropriate Program Manager will direct the auditor on whether or not an additional finding against the corrective action process should be documented.

7 Integrated Management System Audits

- 7.1 Organizations have the opportunity to hold ISO 9001 audits and other management system audits at the same time. At the time of application, the organization must provide evidence of an integrated management system (preferred), or if the client is an implementation stage, provide an attestation that they intend to integrate their management system. Audit days are to be determined using the F-114series. The quoted audit time is to be justified using the F-114. (If a discount is granted for an integrated management system and at the time of the Stage 1 audit, the organization is found not to have an integrated management system, then any Stage 2 discount would be non-applicable).
- 7.2 The Lead Auditor must be competent to audit all standards to which the organization wishes to become certified. If some team members are not qualified to audit all applicable standards, then the Lead Auditor is responsible for planning the audit such that an auditor will not be assigned to audit a standard in which s/he is not competent. The competency of the selected audit team must be justified on the F-114a.
- 7.3 An Executive Committee Member who possesses qualification in each standard of the integrated management system scheme shall make the certification decision. If there is not a single Executive Committee Member who possesses all of the required competence to make the decision, then multiple Executive Committee Members may be used.
- 7.4 A special certificate is issued for each management system standard where certification has been approved.
- 7.5 Integrated management system audits are not to be confused with combined audits. In a combined audit, a client has not integrated common aspects/processes of different management system standards. A combined audit is simply an audit where multiple management systems are audited simultaneously.

8 Certification

- 8.1 Upon completion of the Stage 2 Audit, and resolution of any nonconformities, the PJR Audit Team returns all documentation concerning the audit to the appropriate PJR office. NOTE: Audit working documents, reports and forms generated during an audit are the property of PJR. The Audit Logistics Manager (ALM) or his/her designee reviews the packet for completeness. When PJR is working with a new standard, where technical experts are involved in audit package review and the decision-making, then a review of the package from a management systems perspective may occur first. (The idea is that if there are issues with the package from a management systems perspective, the technical reviewer may not catch these. Thus, for new standards, a team approach to audit package review and decision-making will be used). In an ISO 27001 situation, the documentation and recommendation must be submitted to an Executive Committee Member who has successfully completed ISO 27001 Lead Auditor Training and this member has veto power over any certification decision. For AS91xx audits, the Executive Committee Member reviewing the package must be at least an Aerospace Auditor (AA) authenticated by an AAB. For ACCREDIA audits, 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. For FSSC and ISO 22000 Food Safety audits the certification decision will be made 120 days from the last day of the Stage II or Recertification audit. More on required Executive Committee competencies can be found in PRO-17.
- 8.1.1 Executive Committee Members are trained by the Executive Committee Chair or designee. The Executive Committee Chair records this training on form F-60, or the F-21ec. The Executive Committee Chair will maintain the records of qualified Executive Committee Members. A minimum of two audit packages for each reviewer will be sampled on an annual basis. The Aerospace Program Manager is responsible for completing and/or coordinating this for the aerospace program. The EHS Program Manager is responsible for completing and/or coordinating this for all sustainability programs. The Programs & Accreditations Department is responsible for completing and/or coordinating this for 9001, BA 9000, 13485, 27001, 20000 and TL 9000. The results of this review will be documented on the, F-224, Sampling of EC Reviewed Audit Packages. Results will be discussed at the annual management review.
- 8.1.2 Results of the audit package review are documented on the appropriate F-67.
- 8.1.3 Executive Committee Members and technical reviewers are required to sign the F-71ex, Executive Committee Member Statement of Availability, prior to completing review of an audit package in order to confirm that there is no conflict of interest, as neither the auditor nor the auditor's employer has a relationship with the client.
- 8.1.4 In cases where an Executive Committee Member rejects the package, s/he or another member of the Executive Committee is responsible for contacting the auditor or client for resolution. As appropriate, a member of the Executive Committee or other competent designee is responsible for any auditor re-training.
- 8.1.5 If an audit package is in any language except English, the minimum requirements for translation for review are the audit plan, the Nonconformity Reports and, if required, the objective evidence, and Final Audit Report. If the reviewer requires more information translated, requests may be made.
- 8.1.6 After an affirmative certification decision is made, the audit package is forwarded to a Certificate Coordinator for certificate creation. For Food Safety, the Food Safety Program Manager signs off on the certificate before it is sent to the client for approval. Note: The scope of certification shall not include processes that were not audited to sufficient depth to verify conformance to requirements. Where processes are not audited and are excluded from the scope of certification, any such exclusion shall be limited to those processes that are permissible exclusions and are appropriately substantiated by the client. PJR will not certify a

management system where the process exclusions are not permissible exclusions.

In the case of multi-sited organizations, if any site has a major nonconformity, certification will be denied to the entire organization, pending satisfactory corrective action. It is not permissible for an organization to exclude the problematic site in order to circumvent this.

- 8.1.7 From time to time, Executive Committee Review of the audit package may result in a change to audit report/record. It is important that both the client and PJR have the latest revision of the audit documentation as part of their audit record. The Executive Committee reviewer is responsible for noting the revised audit report/record as such in SharePoint. This way the fact that the audit report/record was revised is made clear to the Audit Logistics supervisor, who is responsible for e-mailing the revised report/record to the client.
- 8.2 Certificates are created in accordance with WI-4. For certificates issued in more than one language, a "t" suffix is used at the end of the certificate number to denote which certificate is the translation.
- 8.3 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 under which it is certified.
- 8.4 PJR maintains a list of Certified 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.

10 Surveillance and Recertification Audits

- 10.1 Surveillance and recertification audits typically follow the same process outlined for Stage 2 audits above. For aerospace surveillance and recertification audits, the client is required to complete and return the F-108asdata and any requested attachments.
- 10.2 The primary purpose of a surveillance audit is to verify the continuing effectiveness and improvement of the client's management system. For this reason, the primary focus of a surveillance audit will include a review of actions taken on nonconformities identified during the previous audit, review of process performance (key performance indicator data and achievement of client's own quality objectives) and associated corrective actions, customer complaints, internal audits, management review, improvement and any changes at the client. 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.
- 10.3 If the auditee uses the logos/marks of PJR or its accrediting bodies, then logo usage must be assessed in accordance with PRO-3.
- 10.4 When assigned to complete a surveillance or recertification audit, the Lead Auditor will receive a copy of any nonconformities documented during the previous surveillance audit, as well as a copy of the Final Audit Report. Auditors are required to verify implementation of corrective action in response to these nonconformities. At their discretion, auditors may also verify the continuing effectiveness of corrective action implemented in response to nonconformities documented during earlier audits in a given cycle. If for some reason the Lead Auditor does not receive a copy of the previous nonconformity reports and Audit Final Report from Headquarters, then they are to request these documents from the auditee. If the auditee does not have the previous nonconformities, then the Lead Auditor must contact Headquarters. The Lead Auditor should indicate their verification of corrective action effectiveness on the part of the Nonconformity Report called "Corrective Action Verified As Effective on Next Audit." Surveillance and Recertification audit packages without evidence of verified nonconformities from the previous audit will be considered incomplete.
- 10.5 For both 6 month and regular 12 month surveillances, a reassessment is necessary. A reassessment should be typically 2/3 of the time spent for the initial audit (Stage 1 and Stage 2).

The re-assessment must be conducted in time to ensure that recertification is granted before the expiry date of the certificate.

- 10.6 Master File Review should take place after the 4th semi-annual surveillance audit or after the second Annual surveillance audit. In a Master File Review, all nonconformities as well as any significant organizational changes or concerns in the audit cycle, are reviewed.
- 10.7 Auditors assigned to complete a recertification audit will receive a copy of the Master File Review (F-118 series) completed on the client's audit history during the given audit cycle. The Master File Review provides a brief summary of nonconformities documented during the certification cycle. Auditors will also receive a copy of all audit reports and any nonconformities/associated corrective actions for the prior cycle. This Master File Review, audit reports for prior audits in the cycle and any nonconformities/associated corrective actions should be reviewed in advance of the recertification audit and serve as an input to audit planning. This documentation provided may indicate that an auditor needs to spend more time auditing a certain process/area based on the client's past performance in audits of that process/area.
- 10.8 Under certain circumstances, PJR may mandate that a Stage 1 audit is conducted before the recertification audit. This would normally occur when there have been significant changes at the auditee or in the auditee's management system or in cases of poor management system performance. The decision about whether or not a Stage 1 audit is needed will be made by the Program Manager or appropriate designee. This decision will be documented on the Master File Review. The severity of circumstances prompting a Stage 1 audit before the recertification, will determine whether or not the Stage 1 is on-site or off-site, the duration of the Stage 1 and if the Stage 1 will be a full Stage 1 as described above or if only certain aspects of the auditee's management system are required to be reviewed. There must be sufficient time between the Stage 1 and the recertification audit for the auditee to address any concerns that might arise during the Stage 1.
- 10.9 Auditors must accept corrective action within 75 days of any surveillance or reassessment audit unless sector-specific rules mandate different deadlines. Corrective action implementation in response to nonconformities documented at a surveillance or reassessment audits may be verified at the very next audit, with the exception of major nonconformities and sector-specific rules (e.g. aerospace) as detailed in PJR Advisory #15.
 - 10.9.1 For any major nonconformity, the PJR Lead Auditor shall define time limits for correction/corrective actions to ensure these can be implemented and verified prior to the expiration of certification. This means that sometimes the auditee must implement corrections/corrective actions in less than 60 days.
 - 10.9.2 If PJR has not completed the recertification audit or is not able to verify the implementation of corrections/corrective actions for any major nonconformity prior to the expiry date of certification, then recertification shall not be recommended. The existing certificate cannot be extended.
 - 10.9.3 In cases where the certificate has expired, PJR can issue a new certificate within six months provided that the outstanding recertification activities are completed, otherwise at least a Stage 2 must be conducted. The effective date of the new certificate shall be on or after the recertification decision. The expiry date shall be based on the prior certification cycle.
- 10.10 Not all surveillance audit packages are reviewed by an = Executive Committee Member. For certain standards, including but not limited to ISO 9001, ISO 14001, R2 etc., Lead Auditors who have demonstrated a high level of competence in their auditing techniques and audit packages such as a high rate of package approvals, Lead Auditor's recommendation of continued certification at surveillance audits is sufficient. This decision is made at the discretion of the Programs and Accreditations Manager or appropriate Program Manager.
- 10.11 However, if any of the following conditions exist, even this group of Lead Auditors will have their packages reviewed by Executive Committee:
 - 10.11.1 Major nonconformities have been identified;
 - 10.11.2 Extension of scope of certification, or
 - 10.11.3 Lead Auditor decides that Executive Committee review is needed.
- 10.12 PJR reserves the right to conduct special or short notice audits during the course of the certification period. PJR conducts special audits within 90 days of the situation/issue creating the need for the special audit. If this is not possible, then exceptions must be approved by the

Programs & Accreditations Manager, who may, in turn, need to gain approval from an external authority. Circumstances that may trigger special or short notice audits include, but are not limited to:

- 10.12.1 Requests for an extension of scope – Requests for extension of scope often require that the organization complete a new application (F-1 series), or, at the discretion of the Program Manager, the organization may provide an explanation of the extension of scope in writing. The Program Manager or designee will review the request for extension of scope and the client'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. Note: This may include addition of a physical site or addition of/change to a product/product category/ (special) process.
- 10.12.2 Significant changes at the organization, including changes in ownership, address/location or key personnel, including the management representative, personnel involved in management system effectiveness or regulatory compliance and, in the case of 13485, those with the capability and authority to assure that only safe and effective medical devices are released. (Note that per the PJR contract, the organization is required to notify PJR in writing about any significant change).
- 10.12.3 Complaints from customers or interested parties of certified organizations or if available data suggests that the client is not continuing to meet applicable criteria;
- 10.12.4 Suspension situations;
- 10.12.5 Significant safety related information becoming known to PJR. Note: This is most often applicable to ISO 13485, but it may be applicable to other standards as well.
- 10.12.6 Significant changes occur which have been submitted by the regulations or have become known to PJR, and which could affect the decision on the client's state of compliance with regulatory requirements.
- 10.12.7 Another type of special audit is a revisit in response to a major nonconformity documented during an audit. Not all major nonconformities warrant a revisit. The need for the revisit is a mutual decision between the Lead Auditor and appropriate Program Manager (or appropriate international equivalent).

10.13 If the organization makes only minor changes to its management system, such changes are assessed by PJR during surveillance audits by evaluating the changes and the associated documentation. During the certification cycle, PJR reserves the right to not only conduct on-site audits but to make inquiries to the certified organization on aspects of the certification and request that the organization provide certain documents, especially in response to a complaint about the organization's management system; periodically review any client statements regarding its operations (e.g. paper or electronic promotional literature, especially as it relates to the scope of certification) or any other means of monitoring the certified client's performance.

10.13.1 Extensions to scope are covered in section 10.12.1. Reductions to scope are covered at the next regularly scheduled audit. Client will be prompted by their Scheduler regarding any changes in the scope of certification, at the time the audit is scheduled. An adjustment in audit time may or may not be required. Scheduler will consult Program Management, as needed, if there is any concern that the reduction to scope is inappropriate, e.g. client's current scope involves design and manufacture of widgets and the scope reduction involves removing design. The scope reduction is communicated to the auditor via the Auditor Assignment Sheet, F-27. Auditor will conduct the audit and complete a Certificate Application to reflect the new scope.

10.14 PJR does not participate in Advanced Surveillance/Reassessment Procedures (ASRP).

10.15 For all standards, with the exception of aerospace, special audits require an audit plan and completion of the special/revisit audit report in the appropriate audit workbook. Nonconformity reports shall be documented, as required. For aerospace audits, special audits require an audit plan. Applicable IAQG Forms AS9101 must be completed.

11 Suspension, Withdrawal or Cancellation of Certification

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

11.2 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.

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

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

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

11.6 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.

12 Disputes

12.1 Disputes are handled in accordance with PRO-10.

13 Business Continuity and Disaster Recovery

Where organizations are affected by such natural disasters as hurricanes, tsunamis and earthquakes or other devastating circumstances including but not limited to threats of terrorism, malicious computer hacking, geopolitical tension, pandemic disasters or labor strikes, PJR will assess each organization's situation individually to determine most appropriate actions. To facilitate this evaluation process, PJR will request organizations to submit the following information:

- 1) To what extent has operation of the management system been affected?

- 2) When will the organization be able to function?
- 3) When will be the organization able to ship products or perform service defined within the current scope of certification?
- 4) Will the organization need to use alternative manufacturing and/or distribution sites? If so, are these currently covered under the current certification or will they need to be evaluated?
- 5) Does existing inventory still meet customer specifications or will clients need to be contacted regarding possible concessions?
- 6) If applicable, is a disaster recovery plan or emergency response plan implemented? Was it effective?
- 7) Will some of the processes and/or services performed or products shipped be subcontracted to other organizations? If so, how will the other organizations' activities be controlled by the certified organization?

Additionally, to ensure continuing system effectiveness and determine suitability of the certification on a short term basis, PJR may request crucial documentation such as management review meeting minutes, corrective actions, results of internal audits, and the status of process controls.

Organizations due for recertification audits that are unable to recertify must re-register after expiration of their certificate. Surveillance audits may be postponed for a maximum of 3 months from the audit due date. Organizations postponing surveillance audits past 3 months must opt for voluntary suspension of their certification. If a client has already delayed their audit by three months, then the voluntary suspension of certification can last additional three months. At the end of the voluntary suspension period, a recertification audit must be conducted, or the certificate will be withdrawn.

14 Confidentiality

- 14.1 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 that comes into its possession in the course of assessment or certification of an organization's management system. At the same time, PJR controls any documents obtained in advance (e.g. manual, organization chart) according to PRO-5. 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 certified company, 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 certified company 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.

15 Witness Assessments

- 15.1 Any organization being audited for the purpose of being issued or maintaining a certificate containing any Accreditation Body 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.
- 15.2 The Lead Auditor being witnessed by an accreditation body must contact the Programs and Accreditations Manager or designee at the audit's conclusion, the purpose of which is to quickly communicate the results of the witness audit to the PJR USA Headquarters. If the auditor being witnessed indicates that there was a nonconformity during the audit, but s/he failed to document it, then the Program Manager will work with him or her so that s/he initiates a Nonconformity, amends all other audit documentation, as appropriate, and forwards this information to the client as soon as possible.
- 15.3 Witnessed assessments are valuable opportunities to gather information for program improvement. Witnessed auditors are encouraged to communicate lessons learned to PJR Program Management personnel for review and possible incorporation into the program.

16 Electronic Signatures

When forms require signatures, PJR expects physical or electronic signatures. Electronic signatures may be digital or in the form of an email with the date and time stamp. When an email is used in lieu of physical signature, the individual sending the email must clearly state that the email is to be used as a substitute for a physical signature. Additionally, signature fields on a form must be filled out "Per email from..." and an email must be saved with the form being signed as evidence. (It is not appropriate for the e-mail to only reside in someone's e-mail records). Typewritten names without a time-stamped e-mail are not acceptable. "Original signature on file" statement is an acceptable alternative provided that such exists for a given audit.

Appendix A: FSSC Multiple sites

1) Certification of multi-site organizations and multi-site sampling (as described in ISO/TS 22003:2013 and ISO/IEC 17021-1:2015) is not applicable to the following food chain categories as listed in ISO/TS 22003:2013: CI, CII, CIII and CIV, DI and DII, I and K.

2) For the food chain categories shown under 1) the Scheme requires that every site shall have:

- a) a separate audit,
- b) a separate report,
- c) a separate certificate, and
- d) every site shall be entered separately in the database.

3) Certification of multi-site organizations as shown in ISO/TS 22003:2013, clause 9.1.5 shall be applicable for the following food chain categories as listed in ISO/TS 22003:2013: A, E, FI, G.

Exceptions - applicable for categories C, D, I and K

The Scheme does offer exceptions for three main categories of organizations shown in section 1), that have multiple sites such as organizations:

- a) where some functions pertinent to the certification are controlled by a head office separate to the site(s),
- b) with different operations at one site,
- c) with off-site activities.

Head office functions

Functions pertinent to the certification but controlled by a head office separate to the site(s) could include for example:

- a) Procurement,
- b) Supplier approval or
- c) Quality assurance.

Auditing head office functions

1) In all cases where functions pertinent to the certification are controlled by a head office, the Scheme requires that those functions are audited interviewing the personnel described in the food safety management system as having the delegated authority and responsibility for these functions.

2) The functions at the head office are audited separately and every site belonging to the group shall have:

- a) a separate audit,
- b) a separate report and
- c) a separate certificate.

Auditing sites in a multi-site organization

1) An audit at the head office cannot assess the degree of implementation at site level.

a) The auditor shall visit the sites to conduct that part of the audit.

b) The head office audit shall be carried out prior to the site audit.

2) The subsequent audit at the site(s) shall include a confirmation that the requirements set out by head office are appropriately incorporated into site specific documents and implemented in practice.

3) The site audit report and certificate shall show which functions have been audited at the head office.

4) The report of the head office audit has a validity of 12 months.

5) The head office cannot take responsibility for all functions within the scope of the certification, and can therefore not receive a separate certificate.

6) The head office is mentioned on the site certificate by use of wording such as "An audit was carried out at (name and location of head office) on DDMMYY to assess the following function(s) (describe functions audited at the head office)".

Dealing with nonconformities

- 1) Where nonconformities are noted in head office or separate sites, these are assumed to have impact on the equivalent procedures applicable to all sites.
- 2) Corrective actions shall therefore address issues of communication across the certified sites and appropriate actions for impacted sites.
- 3) Such nonconformities and corrective actions shall be clearly identified in the relevant section of the audit report.
- 4) The nonconformities shall be cleared in accordance with the CB procedures before issuing the site certificate.

Organizations with different operations at one site

- 1) In cases where different operations are located on one site, for example where a manufacturing operation is linked to a packing operation, both shall be considered for certification under a single scope based on one audit, report and certificate provided that both are:
 - a) subject to one audit appropriate to the combined scope;
 - b) part of the same legal entity.
- 2) The preferred description on the certificate in such cases is to use the name of the legal entity as the primary name. For example: "XYZ company, operating as ABC processing and 123 packaging, (insert address)".

Off-site activities

Split-process

- 1) A certified organization has a (single) process that is split between different sites that shall be part of the same legal entity. The primary site is the sole receiver/customer of the secondary site(s).
 - a) For example, a semi-finished product is moved to a separate site for a specific process step or steps to be carried out, and is returned to the primary location for completion.
 - b) Such processes shall, by exception, be considered for certification under a single scope and one certificate.

Management of off-site activities

The off-site activities shall meet with the following requirements:

- 1) The off-site activities are included in the primary site food safety management system.
- 2) The scope statement of the primary certified site shall show the on-site and off-site activities.
- 3) The audit report shall include all relevant requirements at both the primary and secondary sites and allow audit findings to be identified as site specific.
- 4) The number of secondary sites shall be limited to a maximum of five.

Appendix B: Gluten-Free Certification Program

1. Recognition Process

- Facility submits an application to Allergen Control Group and PJR contracts with the facility
- PJR Schedules a Stage I audit, during which auditor holds a pre-meeting with facility's management to provide information about the recognition and licensing and to review a random selection of components from the facility's written pre-requisite programs and its Gluten-Free Management System.
- Facility submits or provides access to documentation and can be provided at time of Stage 1. The documentation package must include the following:
 - Senior management letter of commitment
 - Gluten-Free Management System performance reporting procedure
 - Name of Gluten-Free Management System team leader
 - Pre-requisite programs
 - List of all products to be produced in the facility
 - Gluten-Free Management System
 - Process Control(s), when applicable
 - Validation data of critical control points
 - Gluten-Free Management System maintenance and reassessment procedures
 - Internal Audit results
- GFCP Approved Auditor reviews facility's documentation in a Stage I audit conducted for .5 day offsite. The GFCP Approved Auditor will communicate and follow up on any unacceptable items to the applicant in writing for correction prior to the final on-site audit. The Gluten Free Stage 1 Workbook is to be completed.
- GFCP Approved Auditor creates an audit plan using (F-184)conducts an on-site audit of the facility's Gluten-Free Management System. The on-site audit is initiated only after the GFCP Approved Auditor has deemed the facility's written Gluten-Free Management System is complete. At the conclusion of the on-site audit, there will be a written report including any non-conformity identified during the on-site audit. ACG's Audit Forms and Guidance is to be used, as well as the PJR Addendum for GF audits. The facility will have 28 days to closeout any and all auditor documented non-conformances and must use PJR's corrective action form in Workbook Supplement (WB-Supp)
- GFCP Approved Auditor will submit final audit report and supporting documentation to PJR for Technical Review. Technical Review of GFCP audit report will be performed by another GFCP Approved Auditor that is independent of the audit. PJR will make a written recommendation on recognition and submit the final completed audit report to the Allergen Control Group Inc. (ACG), for their review and approval process.
- PJR will issue the certificate no later than 42 days from the date of the last day of the on-site audit.
- The ACG may grant an extension to the specified date of completion of the action plan. The facility must submit its reasons in writing to the ACG or to GFCP Approved Auditor through PJR. Only the following reason will be accepted:
 - Product safety or gluten-free status of products are not compromised;
 - The facility will not meet the specified date for completion of corrective actions due to reasons beyond its control;
 - The facility submits a written request for an extension before the specified date for completion of the action plan;
 - The written request includes the reason for the extension request and the proposed new completion date.
- If the corrective action date has passed and the facility has not successfully closed their CAR then the ACG or GFCP Approved Auditor will take the following actions:
 - Warning letter sent to the facility's management.
 - A follow up evaluation of corrective measures is conducted after the date specific in the warning letter. If the corrective measures have been implemented effectively the CAR is closed.
 - If the corrective measures have not been implemented effectively, the facility will lose status as a recognized facility or license under the GFCP and full under suspension or the recognition or license will be cancelled.

2. Audit Frequency

- The audit frequency will be once a year and dependent on whenever the following situations occur:
 - Submission of new Gluten-Free Management System
 - Follow-up after a recall
 - Laboratory results or audits demonstrate that the facility is not delivering its Gluten-Free Management System or fails to conform to other aspects of the requirements of the Gluten-Free Certification Program.
 - Other audits protocol or sampling results deemed to be relevant.
- Where a facility already undergoes a recognized food safety management system audit (such as GMP, HACCP, GFSI standards, FSEP and/or ISO 22000) the GFCP audit may also be combined with that audit for an integrated “one white coat” approach.

3. Suspension or Cancellation

- When a facility loses status under the Gluten-Free Certification Program, the ACG or designate will send a letter to the facility's management informing them that the facility is suspended with conditions or is cancelled. The facility is then temporarily ineligible to participate in the benefits of the GFCP.
- In the case of cancellation, the facility will no longer be eligible to use and must withdraw any product or labels with the Gluten-Free Certification Program Trademark(s) applied including similar words or any advertising making claims regarding their former status under the GFCP.
- The facility must re-apply as a new applicant showing the root cause(s) of the failure of their GFMS and specify corrective measures which must be documented when requesting a new application.

4. PJR Communication with Allergen Control Group

- PJR's Food Safety Program Admin Manager or Designee will provide ACG once per quarter or upon request the following information:
 - Number of current contracts to provide GFCP audit and certification services;
 - Number of GFCP certificates issued;
 - Number of complaints and a report on their nature and resolution;
 - Number of suspensions of GFCP certifications and a report on their nature and resolution; and
 - Number of cancellations of GFCP certifications and a report on the reasons for the cancellations.
- Once the final audit report has been approved by the Technical Reviewer the Food Safety Program Admin Manager or Designee will submit by email the final completed audit report to the Allergen Control Group Inc. (ACG), for their review and approval process.

Appendix C: Virtual Audits

- Virtual audits may be conducted in the following circumstances: Stage 1 audits (with justification); Stage 2, surveillance and recertification audits for organizations whose operations are entirely virtual; special/revisit audits to verify corrective action implementation or changes in ownership; and audits of remote locations providing administrative support, where all management system records are virtual and no additional benefit is gained from a physical audit. Virtual audit techniques are generally not acceptable in a manufacturing environment.
- The Registration Agreement and/or contract amendment must indicate that virtual audit techniques are going to be used and the client must have the necessary infrastructure and competency regarding these techniques. Audit time may need to be added if the virtual audit techniques to be used extend beyond screensharing, i.e. directing a camera operator, for example, may add time. This should be described in the F-114.
- The audit plan should indicate how and when virtual audit techniques are going to be used. Lead Auditor and/or office personnel will do a practice run to confirm the functionality of the technology (GoToMeeting, Sype for Business, cameras and other similiary technology,etc.)
- If the use of virtual audit technology impedes progress of the audit, then the Lead Auditor must communicate this to HQ.
- A description of the virtual audit techniques used must be included in the appropriate section of the WB-Supplement. Auditors should take care to record specific objective evidence so audit trails can be validated, if needed.