QP 4.0	Pre-Audit Registration Procedures	PRI Certification PERFORMANCE REVIEW INSTITUTE

Contents

1.0 Scope

1.1 General

.1 PRI shall conform to the applicable requirements and follow procedures for the assessment and certification of an organization's management system(s) that are consistent with the following, including their reference documents.

.2 The objective of this third-party system is to provide, by means of audit and subsequent surveillance, an adequate level of confidence that the organization's management system conforms to the identified requirements for that system.

.3 This third-party system involves only the auditing of the organization's management system and is not concerned with the certification of product.

.4 The identification of conformance to the appropriate management system standard and any supplementary documentation will be in the form of a registration document.

1.2 References

.1 ISO/IEC 17021 *Conformity assessment - Requirements for bodies providing audit and certification of management systems*, and any related normative document(s), most current revisions.

.2 ISO 19011 *Guidelines for management system auditing*

These procedures are valid for the PRI third party system of assessing and registering an organization's management system to a management system standard and/or sector specific requirement(s).

.3 IAF MD 1 – Certification of Multiple Sites based on sampling. Refer to R20.114, Guidelines For Auditing Multiple Site/Sampling Clients

.4 IAF MD 5 – Mandatory Document Duration for QMS and EMS Audits

.5 MD 22- Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management System

.6 IAF MD 2 – Transfer of Accredited Certification of Management Systems

.7 *General Registration Information* (R20.1)

.8 *ISO Registration Audit Procedures Flow Chart* (R20.11)

.9 *PRI Registration Survey* Series (R20.28)

.10 *PRI Application and Cost Proposal Terms and Conditions* (R20.3)

.11 Proposal Worksheet

.12 PRI Registration Fee Schedule

.13 *PRI Registration Agreement* (R20.4)

.14 *On-Site Audit Procedure* (QP 5.0)

.15 *Post-Audit Registration Procedures* (QP 6.0)

.16 *Post-Registration Procedures (QP 7.0)*

.17 *Appeal Resolution System* (QP 8.0), for use by any party if appeal is desired.

.18 *Recordkeeping and Retention* (QP 10.0)

.19 *Personnel* (QP 11.0)

.20 *Training and Education* (QP 12.0)

.21 *Subcontractor Requirements* (QP 13.0)

.22 *Corrective Action* (QP 15.0)

.23 *PRI Code of Conduct* (R20.10)

.24 *Conflict of Interest Policy* (R20.29)

.25 *PRI Policy Manual Quality Management Systems* (QPM)

.26 *Certification Department Contract Review* (R20.38)

.27 *Transfer of Registration* (R20.118)

.28 *IAAR Guideline on Transfer of Registrations Between Registrars* (R20.101)

.29 *PRI Approaches to Registration Assessments (R20.67)*

1.3 Responsibilities

.1 **President & COO:** shall establish, maintain, and continually improve all registration policies and procedures.

.2 **Certification Department:** under the direction of the Vice President, Certification or designate is responsible for developing, implementing,

managing, and monitoring the management system registration processes.

1.4 Approvals

This procedure has been approved by the Senior Vice President, Audit Operations.

2.0 Procedures

2.1 Application for Assessment

.1 The organization should inquire or request the PRI registration information package and application form. Upon that request, PRI will send to the organization a copy of the current PRI: application form, information package, survey form, and registration agreement.

.2 Upon return of the survey or upon obtaining sufficient information to determine PRI's capability to provide certification/registration services, PRI will project the activities and auditor time needed to support the registration process and forward an estimate of the expected cost to the organization/potential client. For all standards besides ISO 9001 and for initial audits and transfer audits, PRI requires an R20.28XX to be completed (ANAB-OA-AQMS-NCR5). For ISO 9001, the use of the "PRI On-Line Request Basic Information" sheet is acceptable.

.3 The registration approach is identified (See R20.67).

- If the client application requests a sampling approach, PRI uses MD-1 (sections 5 and 6.1) for QMS or EMS registration to determine if sampling is allowed. If an OHS registration is requested, sampling must meet MD-1 (sections 5 and 6.1) AND the requirements of MD-22 (sections G 9.1.5 and Annex B, section B.10.1 and B.10.2).
- If an organization qualifies as a multi-site per MD-1 section 5, but does not meet criteria for sampling, then MD-1 section 6.2 is applied. Some schemes do not allow sampling (e.g., IATF 16949 or AS9100) or have their own unique registration approaches. For those schemes, see scheme specific RForms or procedures for allowed registration approaches and definitions.
  - For sampling or non-sampling multi-site approaches, when a 20% multiple site / corporate discount is applied, the 20% discount is not given at the HQ site and/or the address that holds central functions. The 20% discount may be applied other sites that are part of the multiple site certificate, with the understanding that the reduction of audit time at any individual location cannot be more than 50%.

- Management system audit mandays (based on IAF MD 5 and

Appendix A tables for QMS and Annex B tables for EMS, and MD 22 Appendix B and its tables for OHS) and fees quoted are structured to cover all necessary activities including document review, planning, interfacing with the organization, audit, and final reporting connected with the audit(s). For quoting of other schemes, see scheme specific RForms or procedures.

1) Planning and report writing should not reduce the total on site auditor time to less than 90% of the projected audit time.
2) An auditor day is typically a full normal working day of eight (8) hours. The number of auditor days employed may not be reduced at the initial planning stages by programming longer hours per workday, unless specifically permitted by the registration standard.
3) For the initial registration cycle, surveillance time should be proportional to the time spent at the initial audit with the total amount of time spent annually on surveillance typically one-third (1/3) of the time spent on the initial audit.
4) The amount of time spent at re-assessment should typically be two-thirds (2/3) of the time that would be required for initial assessment.
5) Re-assessment is time spent above and beyond the routine surveillance time. When re-assessment is carried out at the same time as a planned routine surveillance visit, the re-assessment will suffice to meet the requirements for surveillance.

- Once the general starting point has been determined for auditor time, some adjustments may need to be made to account for differences that could affect the time required to perform an effective audit, specifics of the organization (size and number of sites, scope, logistics, outsourcing, complexity, technological or regulatory context, preparedness for the audit, prior audit results, etc.) single or multi-site certification/registration, joint, combined or integrated audits. The duration of the audit and its justifications are recorded. Time spent by any non-member of the audit team (provisional auditor, technical expert, internal witness auditor, translator, etc.) is not counted against minimum audit time.

.4 The *PRI Application and Cost Proposal Terms and Conditions* (R20.3) includes information regarding applicant obligations prior to the registration audit and provides evidence of official agreement.

.5 The survey or online request or other request such as e-mails and application should be returned to PRI, completed fully in English, covering all applicable organizations and locations, along with management system documents, and any application fee required (reference PRI Registration Fee Schedule).

2.2 Establishing the Registration Process

.1 After receipt of the survey, formal proposal acceptance, and receipt of an application signed by a duly authorized representative of the applicant, PRI will begin processing the application, provide additional information concerning the PRI registration process, PRI registration procedures and any other applicable documentation. Additional information will be requested of the organization relating to the organization's readiness, and scheduling of the pre-audit documentation review, information collection and feedback visit and/or any pre-assessment. PRI may, with the agreement of the organization, appoint an auditor to undertake either the initial assessment (in full or in part) or surveillance or both under its authority and responsibility, performed under agreed conditions.

If, for any reason, PRI decides to refuse consideration, the organization is informed. After receipt of the survey or other relevant information by other means, a written proposal is prepared to start the formalization of a contract agreement.

A. Request additional information of the supplier relating to the organization's:

1) readiness, and
2) scheduling of any pre-assessment audit, Stage 1 (document review, audit preparedness evaluation, information collection and feedback visit), and scheduling of the Stage 2 (on-site audit). PRI may, with the agreement of the supplier, appoint an auditor to undertake either the initial assessment (in full or in part), surveillance, or both under its authority and responsibility, performed under agreed conditions.

.2 Before proceeding with the audit, the PRI Contract Review function will review and document the review of the application and survey and be confident that:

A. The scope of the desired registration is defined;

B. The applicant agrees to comply with the requirements for registration and provide any information needed for its evaluation;

C. The general features of the applicant, when applicable, such as corporate entity, name, address, legal status, human and technical resources are clearly identified;

D. A description of the management system to be registered, including requirements to which the organization subscribes and the system standard and/or sector specific requirement(s) or other normative documents are identified. Confirm the R20.28XX is complete as required in step 2.1.2 above. For ISO 9001 only, confirm the

R20.28 and or the “PRI On-Line Request Basic Information” sheet is complete as required in step 2.1.2 above. Review the proposed registration approach on the quote vs. the requirements of the R20.67 and resolve any related issues;

E. The requirements for registration have been clearly identified, documented, and understood by the applicant;

F. Any differences in understanding between PRI and the applicant regarding the terms and conditions, registration process, and/or registration agreement are resolved;

G. PRI has the capability to perform the registration service with respect to the scope of the registration, the location of the applicant’s operations, and special requirements such as the language used by the applicant.

.3 When the review identifies areas of concern, any differences are resolved with the applicant and confirmed in writing. If the application materials are acceptable, PRI may formalize a contract agreement. Should PRI decline to accept an application for any reason, that decision and the reason(s) are communicated to the applicant in writing. The contract/proposal will be stamped, dated indicating acceptance, and constitutes evidence of completed application review.

A. For transfer audits, the R20.118, Transfer of Registration form, is utilized.

.4 PRI is responsible for all the phases of an audit. This includes the initial and follow-up surveillance audits.

.5 After the application has been reviewed and any questions are resolved, PRI will make the necessary arrangements with the organization, in accordance with the rules of the program, for:

A. Any pre-assessment and Stages 1 and 2 of the audit,

B. Examination of documents,

C. Audit of all areas,

D. Resolution of complaints,

E. Surveillance,

F. Re-audit,

G. Records and Interview of personnel for the purpose of the audits.

2.3 Audit Team Selection

.1 Before being assigned direct responsibilities for a specific registration, lead auditors are approved by the Auditor Review Board. Auditors and technical experts are approved by PRI's Vice President, Certification. For 9K, 14K or 45K audits, auditor assignment is based on BOTH the IAF code and the applicable Technical Area code.

A. If Scheduling wants to assign an auditor who lacks the appropriate competency codes, then contact Certification so the competency expansion process can be initiated (see QP 11.0, 2.4.3.D).

B. For ISO 9001 events, if a technical area code (IAF-sequential #) per R20.41I does not generate on the assignment page, then Scheduling contacts Certification. Certification will review the auditor's technical competency vs. the organization's code. If they match, Certification will notify Scheduling that the auditor may be applied to the client.

- Likewise, if technical codes related to 14K or 45K do not generate on the assignments page, Scheduling will contact Certification for resolution as described above.

C. If the auditor's codes do not match the organization, then Certification can assess competency limited to a specific organization's scope. If an auditor can demonstrate competency for a specific organization's scope, then Scheduling will establish a record via a Special Considerations comment tied to the organization. This form of approval is organization specific and does not qualify the auditor across the full scope of the technical area code.

- If the auditor cannot demonstrate competency, then Certification will contact Scheduling so a different auditor can be selected.

.2 The process for selecting audit team members for a specific registration will ensure that the audit teams possess the overall experience, expertise, and skills to conduct the audit. Impartiality is also evaluated as part of the audit team selection. The audit team will have at least one member experienced in the technology/industry concerned. Scheduling or designate, under the direction of the Certification Department, selects the audit team using the following as a basis for assignment:

A. Qualifications as given, education, experience, training, personal attributes, management attributes, and the competence to achieve audit objectives of an individually assigned auditor or of the team as a whole;

B. Audit objectives/scope/criteria/type (single, combined, integrated, sampling), size and type of organization, processes, activities, or functions being audited;

C. Collectively, language skills and expertise of the audit team

members; if an interpreter is required, they are selected such that they cannot unduly influence the audit.

D. Requirements of the client (including geographic, cultural and social issues, if applicable), PRI and accreditation bodies;

E. Familiarity with applicable legal regulations, management system standard and/or sector specific requirement(s), registration procedures, and registration requirements;

F. Knowledge of the relevant audit method and audit documents;

G. Technical knowledge of the specific activities for which registration is sought, and where relevant, associated procedures and their potential for failure;

H. General understanding in the technological and industrial sector sufficient to make a reliable assessment of the competence of the organization to provide products, processes, or services in its registered scope.

I. Communication skills both written and oral in the required language;

J. Be free from any interest that may cause team members to act in other than an impartial or nondiscriminatory manner, for example:

- provided consulting services to the applicant or organization,
- past, present, or future consideration for employment with the applicant, organization, or related bodies.

.3 Prior to the audit, all audit team members will sign *PRI's Conflict of Interest Policy*, *PRI Code of Conduct,* and shall inform PRI about any existing, past, and envisioned future links between themselves or their organizations and the organizations to be audited or related bodies of the organization to be audited.

.4 One member of the team will be assigned as the lead auditor and will be responsible for managing the audit process, including assignment of responsibility to each team auditor. If audit assignments are altered from the published audit plan, the lead auditor will hand amend the plan as a basis the final audit plan. Auditor-in-training may be assigned (i.e., provisional or acting leads), along with a competent evaluator. Evaluators are responsible to ensure audit objectives are satisfied and are authorized to take over duties of the auditor-in-training as needed.

.5 The organization shall be informed of the names of the audit team members with sufficient notice to appeal against the appointment of any member. The organization has the absolute right of objection to a named

auditor where conflict of interest may arise.

2.4 Pre-Audit Documentation Review

.1 The organization is required to have a documented system which conforms to applicable system standards (e.g., ISO 9001, ISO 14001) as supplemented, if necessary, by relevant industry sector requirements. Before an assessment visit is arranged, a detailed appraisal of the organization's system documentation for conformance with the applicable requirements is undertaken by PRI. This may occur at Stage 1 or by submission of a copy of the applicant's management system manual to PRI. Included in the documentation is a matrix (R20.44X) which indicates the organization's processes. The organization is notified of any significant omissions or deviations from the requirements in order that suitable amendments can be made prior to the Stage 2 registration audit. A maximum of two (2) complete manual reviews may be conducted, after each of which the registrant must resolve the manual disparities. An implementation period of two to three months is typically required to ensure sufficient maturity of the system for an acceptable audit. The maximum time allowed by PRI between final documentation review and certification assessment is typically no less than thirty (30) days or more than six (6) months.

.2 An optional pre-audit documentation review visit to the organization's site can be scheduled. In preparation for the visit by the lead auditor, the organization shall ensure that:

A. All documentation relating to the system for which registration is sought, including the manual or its equivalent, is made available to the lead auditor.

B. All pertinent records relating to implementation of the system are made available to the lead auditor.

C. PRI assessors are permitted and assisted to undertake assessment of the system.

D. Responsibility to PRI for the system is clearly defined, for example by appointing a designated person to ensure that the PRI procedures are observed.

.3 For a detailed definition of the activities expected for a pre-audit document review visit, refer to the *An Explanation of Stage 1 On Site Audit* (R20.8).

.4 The lead auditor will use the status of the documentation as a guide to recommend to PRI the readiness of the organization for an assessment, and the appropriate timing of the audit.

2.5 Audit Planning

1. In conjunction with the pre-audit document review, the lead auditor works with the organization to develop all components of the Audit Plan for the pre-assessment, when applicable, or the registration audit, including scheduled on-site communications. For a single site, the audit plan covers the entire scope. For a multi-site, the audit plan at each site may cover a portion of the certification scope with plans across all included sites covering the entire certification scope. The Stage 1 or 2 plan should, if applicable, address:

   A. The audit objectives (conformity of management system, its ability to meet statutory, regulatory, and contractual requirements, its effectiveness in achieving its defined objectives, identification of any applicable opportunities for improvement) scope, audit team identification and size (including non-auditor technical experts), and legal guidelines;

   B. The audit criteria (requirements of defined normative documents for the management system and the defined documents and processes of the client's system);

   C. Identification of the auditee's organizational and functional units or processes, shifts to be audited, and their location(s);

   D. Identification of the functions or individuals having significant direct responsibility for the auditee's management system and establishment of a formal auditee "contact;"

   E. Identification of those process(es)/clause(s) of the management system that are of high audit priority;

   F. The procedures for auditing the management system process(es)/clause(s), including special audit requirements (if any) when the management system shares process(es)/clause(s) or is influenced by other management system(s);

   G. Obtaining organization materials needed for team preparation;

   H. The working and reporting language of the audit (English);

   I. Identification of reference documents;

   J. The expected time and duration of major audit activities;

   K. The date and place(s) where the audit(s) is to be conducted, including, as needed, the visit to temporary or field locations;

   L. Meeting schedules with the auditee's management;

M. Confidentiality requirements;

.2 A formal notification letter containing the major process (es)/clause(s) of the audit plan will be sent to the organization typically three weeks prior to the scheduled event. The audit plan and date of the audit will be agreed to with the organization. If the organization objects to any provisions in the audit plan, such objections should be addressed to the lead auditor and resolved between the lead auditor and organization before conducting the audit. Any revised audit plan should be agreed to between the lead auditor and organization before or during the audit.

2.6 Pre-Assessments

.1 Audit team members shall not provide advice or consultancy prior to, as part of, or following any pre-assessment. Outside the registration process, PRI may conduct pre-assessments of the management system according to the organization's needs. Pre-assessments will be conformance audits structured so that the same subjects and/or process(es)/clause(s) are not audited more than twice before the registration audit.

.2 In preparation for the pre-assessment, the organization shall ensure that:

A. All necessary arrangements for the conduct of the audit are completed and satisfactory for an effective visit;

B. All documentation, records, other information, audit areas, and personnel needed for the purpose of the audit are made available to the auditor(s);

C. PRI auditor(s) are permitted access and assisted to undertake the audit of the management system;

D. Responsibility to PRI for supporting the management system audit is clearly defined, for example notification to all levels of the organization about the audit and by appointing a designated person to ensure that the PRI procedures are observed.

.3 Typically, the audit team will meet on-site before starting the pre-assessment to:

A. Review logistical issues and pre-audit preparation materials;

B. Review agenda, audit materials, legal guidelines, and individual assignments;

C. Conduct final briefings and obtain additional information, if needed;

D. Arrange and complete a familiarization tour, as needed;

E. If appropriate, arrange informal contact with auditee.

.4 A formal meeting is held by the audit team with the organization's management on the premises prior to the start of the pre-assessment. The meeting checklist (R20.19) is used to standardize the communication within the meeting. The purpose is to:

A. Make introductions and pass the attendance sheet;

B. Present scope, purpose;

C. Present "agenda/plan," confirm suitability;

D. Review notebook, audit procedures, and legal guidelines;

E. Set up communication links with organization;

F. Arrange for authorization guides and describe limitations on their role, office space, lunch, etc.;

G. Schedule mini-reviews after each audit segment (no surprises);

H. Review methods for handling noncompliance to environmental laws and regulations, if applicable;

I. Answer any questions;

J. Listen to management statements;

K. Make post-audit conference arrangements;

.5 At the end of the audit, a meeting is held with the auditee's management and those responsible for the functions concerned. The purpose is to present the audit results in such a manner as to obtain from the auditee a clear understanding and acknowledgment of the factual basis of any nonconformity and, to assure clear communication and understanding of audit observations. Final decisions regarding significance and description of the audit findings rests ultimately on the lead auditor, though the auditee may disagree with these findings. At the meeting, the auditor(s):

A. Reconfirm top management involvement;

B. Reintroduce audit team;

C. Pass attendance log; obtain audit team signatures on required forms;

D. Summarize agenda/plan and deviations in implementation;

E. Summarizes “Strengths” and “Areas for Improvement;”

F. Summarize the management system and organization’s degree of conformance/preparedness for a registration audit, including details of any significant omissions or deviations from the requirements in order that suitable amendments can be made prior to the registration;

G. Agree on the details of the registration audit;

H. Complete corrective action notification forms, discuss, obtain organization signature, and leave a copy with the organization. While these corrective action notifications are not mandatory, we ask that the organization “exercise” their system, and resolve any identified issues so that at the registration event, the same issues will not surface;

I. Discuss improvement action (plans) and potential follow-up planning schedules;

J. Summarize PRI reporting, corrective action, and review procedures;

K. Receive and note organization management comments;

L. Review PRI’s complaints, appeals, and dispute system;

M. Resolve or report any disputes or appeals;

N. Recognize cooperation and hospitality before adjournment.

.6 The lead auditor will use results from the pre-assessment as a guide to recommend to PRI the preparedness of the organization for the registration audit, and the appropriate timing of the audit.

.7 After a pre-assessment, the organization is provided a report presenting results of the audit in a format suitable for the type of audit conducted.

2.7 Team Orientation

.1 Before the physical audit, each team auditor receives a copy of the audit plan, any additional information or documentation needed a notebook/checklist, previous audit considerations, and communication from PRI and the lead auditor relative to preparation and travel.

.2 As appropriate, each audit team member will be assigned by the lead auditor to audit specific management system process(es)/clause(s), functions, or activities. Also, the lead auditor will instruct the team on the

audit procedure to follow. During the audit, the lead auditor may make changes to work assignments to ensure optimal achievement of the audit objectives. When changes are made, the lead auditor shall inform the organization and seek their agreement.

.3 PRI may send the working materials and other items to the organization's contact to hold for team arrival.

3.0 Records

3.1 *PRI Application and Cost Proposal Terms and Conditions* (R20.3).
3.2 *PRI Registration Survey* (R20.28).
3.3 *Registration Audit Plan* (R20.31) and Notification Letter
3.4 *PRI Assessment Documentation - Corrective Action Notification* (R20.35)
3.5 PRI Audit Report
3.6 PRI Process Matrix – R20.44x
3.7 Applicable Administration Records